EXHIBIT J - PART 1 OF 2

DOCKET NO.: CELG-0508 **PATENT**

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of:

Bruce A. Williams, Joseph K. Kaminski

For: Methods For Delivering A Drug To A Patient While Restricting Access To The Drug By Patients For Whom The Drug May Be Contraindicated

EXPRESS MAIL LABEL NO: EV 816191675 US
DATE OF DEPOSIT: May 19, 2006

EV816191675US

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

PATENT APPLICATION TRANSMITTAL LETTER

Transmitted herewith for filing, please find:

☒ A Continuation Application under 37 CFR § 1.53(b).

The above-identified application includes the following:

☐ A Request for Nonpublication

☐ A Specification including claims and abstract on pages 1 to .

☒ A copy of the specification including claims and abstract (pages 1-24) and drawings and appendixes (if any) of earlier Application No. 11/028,144 filed January 3, 2005, to which no new matter has been added. Such earlier application is hereby incorporated into the present application by reference.

☐ A New Unexecuted Declaration or Oath and Power of Attorney.

☐ A New Executed Declaration or Oath and Power of Attorney.

☒ A copy of the executed oath or declaration filed in parent Application No. 11/028,144, filed on January 3, 2005 is attached.

☐ An Associate Power of Attorney executed by who is listed in the copy of the executed Declaration and Power of Attorney filed herewith.

☐ A Copy of the Power of Attorney with Revocation filed in prior Application No.

☐ Signed Statement deleting inventor(s) named in the prior application.

☐ This application claims foreign priority under 35 U.S.C. § 119 of Application No. filed in (Country).

☐ A Certified Copy of each of the above applications for which priority is claimed:

☐ is enclosed.

☐ has been filed in prior Application No. filed .

☐ Sheets of Formal Drawings and/or Photographs.

☐ Figure should be published.

☐ Petition to Accept Color Photographs is enclosed.

☒ This continuation application is assigned of record to Celgene Corporation as evidenced by the assignment recorded on April 23, 2003 at Reel No. 013982 and Frame No. 0697.

☐ A newly Executed Assignment transferring rights to .

☐ A Recordation Form Cover Sheet.

☐ Recordation Fee - $40.00.

☒ A Preliminary Amendment is enclosed .

☒ An Application Data Sheet is enclosed.

☐ A Sequence Listing consisting of pages 1- .

☐ Diskette containing Sequence Listing is enclosed.

☐ The computer readable form in the above-identified application is identical with that filed in Application Number , filed . In accordance with 37 CFR § 1.821(e), please use the sequence listing filed on and received by the PTO on as the computer readable form filed in that application as the computer readable form for the instant application. It is understood that the Patent and Trademark Office will make the necessary change in application number and filing date for the computer readable form that will be used for the instant application.

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☐ A paper copy of the Sequence Listing:

☐ was filed in the above-identified parent application on and received by the PTO on .

☐ is included herewith in a separately filed preliminary amendment for incorporation into the specification.

☐ A Statement to Support Submission of Sequence Information is enclosed.

☐ Information Disclosure Statement including:

☐ Form 1449.

☐ Copies of References - listed on the attached Form PTO-1449.

☐ A copy of Petition for Extension of Time as filed in the prior case for copendency.

☐ Appended Material as follows: .

☒ Return Receipt Postcard (should be specifically itemized).

FEE CALCULATION:

☐ Applicant(s) by its/their undersigned attorney, claims small entity status under 37 CFR § 1.27 as *(CHOOSE ONE: an Independent Inventor, a Small Business Concern, or a Nonprofit Organization).*

DOCKET NO.: CELG-0508 **PATENT**

			SMALL ENTITY		NOT SMALL ENTITY	
			RATE	FEE	RATE	FEE
UTILITY APPLICATION BASE FEE			$150.00		$300.00	300.00
UTILITY EXAMINATION FEE			$100.00		$200.00	200.00
UTILITY SEARCH FEE			$250.00		$500.00	500.00
UTILITY APPLICATION SIZE FEE			$125.00 for each additional 50 pages over the first 100		$250.00 for each additional 50 pages over the first 100	
UTILITY APPLICATION; ALL CLAIMS CALCULATED AFTER ENTRY OF ALL AMENDMENTS						
	No. Filed	No. Extra				
TOTAL NO. OF CLAIMS	11 - 20 =	0	$25 each		$50 each	0.00
NO. OF INDEPENDENT CLAIMS	1 - 3 =	0	$100 each		$200 each	0.00
MULTIPLE DEPENDENT CLAIM FEE			$180		$360	
ADDITIONAL FILING FEE						
TOTAL FILING FEE DUE						1,000.00

☒ A Check in the amount of **$1,000.00** is attached. Please charge any deficiency or credit any overpayment to Deposit Account No. 23-3050.

☐ Please charge Deposit Account No. 23-3050 in the amount of **$ .00**. This sheet is attached in duplicate.

☒ The Commissioner is hereby requested to grant an extension of time for the appropriate length of time, should one be necessary, in connection with this filing or any future filing submitted to the U.S. Patent and Trademark Office in the above-identified application during the pendency of this application. The Commissioner is further authorized to charge any fees related to any such extension of time to Deposit Account No. 23-3050. This sheet is provided in duplicate.

☒ **Address all correspondence to Customer No. 23377.**

SHOULD ANY DEFICIENCIES APPEAR with respect to this application, including deficiencies in payment of fees, missing parts of the application or otherwise, the United States Patent and Trademark Office is respectfully requested to promptly notify the undersigned.

Date: May 19, 2006

Angela Verrecchio
Registration No. 54,510

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Date: May 19, 2006

Angela Verrecchio
Registration No. 54,510

METHODS FOR DELIVERING A DRUG TO A PATIENT WHILE RESTRICTING ACCESS TO THE DRUG BY PATIENTS FOR WHOM THE DRUG MAY BE CONTRAINDICATED

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application is continuation of U.S. application Serial No. 10/383,275, filed March 7, 2003, which is a continuation of U.S. application Serial No. 09/965,155, filed September 27, 2001, now U.S. Pat. No. 6,561,977, which is a continuation of U.S. application Serial No. 09/694,217, filed October 23, 2000, now U.S. Pat. No. 6,315,720, the entirety of each of which is incorporated herein by reference.

FIELD OF THE INVENTION

[0002] The present invention relates to improved methods for delivering a drug to a patient. More particularly, the present invention relates to novel methods for delivering a teratogenic or other potentially hazardous drug to a patient in need of the drug, while avoiding the occurrence of known or suspected side effects of the drug. The novel methods permit the distribution to patients of drugs, particularly teratogenic drugs, in ways wherein such distribution can be carefully monitored and controlled.

BACKGROUND OF THE INVENTION

[0003] Many beneficial drugs are known or suspected of producing adverse side effects in certain individuals. These side effects may be manifest in the patient taking the drug, in a foetus (i.e. fetus) carried by the patient, or in a recipient (or foetus carried by a recipient) of the bodily fluids of the patient. In some cases, administration of the drug may be acceptable in some patients, but absolutely contraindicated in other patients. For example, drugs known or

suspected of causing birth defects if taken by a pregnant woman (i.e. teratogenic drugs), may nonetheless be beneficial for treating certain conditions. However, because of the teratogenic properties of the drug, administration to pregnant women must be avoided. Other drugs are known which may be beneficially employed in the general population, but must be avoided by individuals having a certain preexisting condition, or those concurrently taking certain other medication(s), due to adverse side effects which may develop in those individuals.

[0004] One such drug which is known to produce adverse side effects, but which may nevertheless be beneficially employed in certain patients is thalidomide. Thalidomide is a drug which was first synthesized in Germany in 1957. Beginning in 1958, it was marketed in many countries for use as a sedative, although it was never approved for use in the United States. After reports of serious birth defects, thalidomide was withdrawn from all markets by 1962. However, during the years it was used, it was found to be effective in treating erythema nodosum leprosum (ENL), a condition of leprosy, and the U.S. Food and Drug Administration (FDA) has made the drug available for this specific use via a program of the Public Health Service. More recently, investigators have found that thalidomide may be effective in treating AIDS wasting and aphthous ulcers occurring in AIDS patients. In addition, treatments for other diseases, such as a number of neoplastic diseases including cancers, rheumatoid arthritis, and macular degeneration, are also believed to be possible. The FDA has recently approved an application by Celgene Corporation, which is the assignee of the present patent application, to market thalidomide for the treatment of ENL. The medical community anticipates that thalidomide will be used for treatment of additional conditions and diseases, including those set forth above. However, due to the severe teratogenic risk of thalidomide, methods are needed to control the distribution of this drug so as to preclude administration to foetuses.

[0005] In this regard, U.S. Patent No. 6,045,501, to Elsayed et al., provides methods for delivering a drug to a patient while preventing the exposure of a foetus or other contraindicated individual to the drug. According to the methods of this patent, prescriptions for the drug are filled only after a computer readable storage medium has been consulted to assure that the prescriber is registered in the medium and qualified to prescribe the drug, that the pharmacy is registered in the medium and qualified to fill the prescription for the drug, and the patient is registered in the medium and approved to receive the drug. Improvements to this method may be useful, however, to minimize and simplify the demands on the pharmacy, thereby improving compliance with the system of distribution, and reducing the risk that the drug will be dispensed to a contraindicated individual.

[0006] Methods for monitoring and educating patients to whom a drug is distributed have been developed in connection with Accutane (isotretinoin). Accutane, which is a known teratogen, is a uniquely effective drug for the treatment of severe, recalcitrant, nodular acne. A pregnancy prevention program was developed, and the Slone Epidemiology Unit of Boston University designed and implemented a survey to evaluate these efforts. The survey identified relatively low rates of pregnancy during Accutane treatment, which suggests that such a program

can be effective. With more than about 325,000 women enrolled to date in the Accutane survey, it is also clear that such a large-scale study can be conducted. Enrollment in the Accutane survey is voluntary, however. Accordingly, assessing the representativeness of the women who have been enrolled in the survey has been problematic, and it has been difficult to determine whether the survey results can be generalized to all female Accutane users. Thus, an improved survey is needed which would be representative of all users of a particular drug, such as thalidomide, who obtain the drug through legal distribution channels. There are also no mechanisms provided to assure compliance with the program or to limit distribution of the drug to participants in the survey.

[0007] Because drug sharing may frequently occur among AIDS patients, which may result in placing a foetus at risk, a program is needed which can be used to educate men and women about the risk of teratogenic drugs, such as thalidomide. In addition, a system is needed for the controlled distribution of a drug, in which of all users of the drug, including prescribers, pharmacies, and patients, may be accountable for their compliance with methods that may be established to minimize the risk that a contraindicated individual will be exposed to the drug. The present invention is directed to these, as well as other important ends.

SUMMARY OF THE INVENTION

[0008] The present invention is directed to improved methods for delivering a drug to a patient in need of the drug, while avoiding the occurrence of an adverse side effect known or suspected of being caused by the drug, of the type in which prescriptions for the drug are filled only after a computer readable storage medium has been consulted to assure that the prescriber is registered in the medium and qualified to prescribe the drug, that the pharmacy is registered in the medium and qualified to fill the prescription for the drug, and the patient is registered in the medium and approved to receive the drug. In one embodiment of the invention, there are provided improved methods comprising the steps of:

[0009] a. defining a plurality of patient risk groups based upon a predefined set of risk parameters for the drug;

[0010] b. defining a set of information to be obtained from the patient, which information is probative of the risk that such adverse side effect is likely to occur if the drug is taken by the patient;

[0011] c. in response to the information set, assigning the patient to at least one of the risk groups; and

[0012] d. entering the risk group assignment in the medium before the patient is approved to receive the drug.

[0013] The improved methods described herein provide advantageous and effective means for monitoring, controlling and authorizing the distribution to patients of drugs known or suspected of causing adverse side effects. The methods of the present invention include a variety

of checks and balances which serve to limit unauthorized and possibly inappropriate distribution of the drug. These methods are particularly applicable to distribution of teratogenic drugs, in which case the checks and balances may be particularly advantageous for preventing distribution of the drug to patients whose use of the drug may pose an unacceptable risk that a foetus carried by the patient or a recipient of the bodily fluids of the patient will be exposed to such drugs. Accordingly, the present methods may be advantageously used to avoid exposure of foetuses to teratogenic drugs, thereby avoiding the terrible birth defects which may result from such exposure.

[0014] The invention is not limited to the distribution of teratogenic drugs; other potentially hazardous drugs may also be distributed in accordance with embodiments of this invention and such drugs may be distributed in such a fashion that persons for whom such drugs are contraindicated will not receive them. These and other aspects of the invention will become more apparent from the present description and claims.

DETAILED DESCRIPTION OF ILLUSTRATIVE EMBODIMENTS

[0015] The present invention is directed generally to methods for the delivery of drugs known or suspected of causing an adverse side effect, especially teratogenic drugs, to patients. The term "drug," as used herein, refers to any substance which is intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease, or to affect the structure or function of the body. The term "side effect" refers to any abnormality, defect, mutation, lesion, degeneration or injury which may be caused by taking the drug. The side effect may be one which is likely to arise in the patient or in a foetus (i.e., fetus) carried by the patient. The side effect may also be one which is likely to arise in a recipient of the bodily fluid of the patient, or foetus carried by such recipient. The term "likely to arise" means that the side effect known or suspected of being caused by the drug may be expected to occur at a higher incidence rate in a particular individual or group of individuals.

[0016] Generally speaking, the methods of the present invention may be desirably and advantageously used to educate and reinforce the actions and behaviors of patients who are taking a drug, as well as prescribers who prescribe the drug and pharmacies which dispense the drug. As used herein, the term "prescriber" refers to any individual who is capable of prescribing drugs, including, for example, a medical doctor. Such education and reinforcement of actions and behavior are often necessary to ensure proper prescribing and dispensing of the drug, as well as patient compliance with taking the drug. A wide variety of educational materials may be employed to ensure proper prescribing, dispensing and patient compliance according to the methods described herein, including, for example, a variety of literature and other materials, such as, for example, product information, educational brochures, continuing education monographs, videotapes and the like which may describe the risks and benefits associated with taking the particular drug and measures which may be taken to avoid those risks.

[0017] The methods described herein may be advantageously employed to avoid delivery of one or more drugs known or suspected of causing an adverse side effect to a patient for whom the drugs may be contraindicated. As used herein, the term "contraindicated" refers to any condition in a patient which renders a particular line of treatment, including the administration of one or more drugs, undesirable or improper. This condition may be preexisting, or may develop while the patient is taking the drugs, including conditions which may result directly or indirectly from treatment with the drugs. Thus, contraindicated drugs include, for example, teratogenic drugs whose administration, for example, to pregnant patients is importantly avoided due to the risks to the foetus. Drugs may also be considered "contraindicated," as the term is used herein, if use of a drug by patients who are also taking another drug is known or suspected of producing an adverse side effect in those patients, or in a foetus carried by such patients.

[0018] The methods of the present invention are especially advantageously employed for the delivery to a patient of a teratogenic drug. The delivery of a teratogenic drug to a patient may be advantageously achieved with the present methods while substantially (including completely) avoiding the delivery of the drug to a foetus. The term "substantially," as used in reference to avoiding the delivery of a teratogenic drug to a foetus, generally means that there is an avoidance rate of delivering the drug to a foetus of greater than about 50%. Preferably, the avoidance rate is greater than about 55%, with an avoidance rate of greater than about 60% being more preferred. Even more preferably, the avoidance rate is greater than about 65%, with an avoidance rate of greater than about 70% being still more preferred. Yet more preferably, the avoidance rate is greater than about 75%, with an avoidance rate of greater than about 80% being still more preferred. In even more preferred embodiments, the avoidance rate is greater than about 85%, with an avoidance rate of greater than about 90% being yet more preferred. Still more preferably, the avoidance rate is greater than about 95%. In particularly preferred embodiments, a teratogenic drug may be delivered to patients with completely no delivery to foetuses (*i.e.*, 100% avoidance rate).

[0019] The drug delivery methods of the present invention preferably involve, *inter alia*, registering in a computer readable storage medium prescribers who are qualified to prescribe the involved drug, including, for example, teratogenic drugs. Once registered in the computer readable storage medium, the prescriber may be eligible to prescribe the drug to patients in need of the drug. Generally speaking, in order to become registered in the computer readable storage medium, the prescriber may be required to comply with various aspects of the methods described herein including, for example, providing patient education and counseling, and the like, as described in detail below. The registration of the prescriber in the computer readable storage medium may be achieved by providing the prescriber, for example, by mail, facsimile transmission, or on-line transmission, with a registration card or form, preferably together with appropriate educational materials concerning, for example, the particular drug for which the prescriber is being registered to prescribe, as well as suitable methods for delivering

the drug to the patient, including the drug delivery methods described herein. The prescriber will preferably complete the registration card or form by providing information requested therein, and the registration card or form will preferably be returned to the manufacturer or distributor of the drug, or other authorized recipient of the registration materials, for example, by mail, facsimile transmission or on-line transmission. Information which may be requested of the prescriber in the registration card or form may include, for example, the prescriber's name, address, and affiliation, if any, with one or more health care institutions. The prescriber's information in the registration card or form is then entered into the computer readable storage medium. It is contemplated that the registration of the prescriber into the computer readable storage medium may also be achieved, for example, by telephone, and/or through the use of an integrated voice response system. Suitable computer readable storage media which may be employed for registration of the prescribers (as well as the pharmacies and patients, as discussed below) will be apparent to one of ordinary skill in the art, once armed with the teachings of the present application.

[0020] In accordance with the methods described herein, pharmacies who are qualified to fill prescriptions for the particular drug being prescribed including, for example, teratogenic drugs, are also preferably registered in a computer readable storage medium. The computer readable storage medium in which the pharmacies are registered may be the same as, or different from the computer readable storage medium in which the prescribers are registered. Once registered in the computer readable storage medium, the pharmacies may be eligible to dispense the involved drug to patients who are in need of the drug. Generally speaking, in order to become registered in the computer readable storage medium, the pharmacy may be required to comply with various aspects of the methods described herein including, for example, registering the patient (preferably also in a computer readable storage medium), ensuring that the patient complies with certain aspects of the drug delivery methods, as well as other aspects of the present methods, as described in detail below. As with the registration of the prescriber in the computer readable storage medium, the registration of the pharmacy may be achieved by providing the pharmacy, for example, by mail, facsimile transmission, or on-line transmission, with a registration card or form, preferably together with appropriate educational materials concerning, for example, the particular drug for which the pharmacy is being registered to dispense, as well as suitable methods for delivering the drug to the patient, including the drug delivery methods described herein. The pharmacy may then have the registration card or form completed by providing the information requested therein, which thereafter may be returned to the manufacturer or distributor of the drug, or other authorized recipient of the registration card or form, for example, by mail, facsimile transmission or on-line transmission. Information which may be requested of the pharmacy in the registration card or form may include, for example, the pharmacy's name, address, and affiliation, if any, with any health care institution such as, for example, a hospital, health care organization, and the like. The pharmacy's information in the registration card or form is then preferably entered into the computer readable

storage medium. It is contemplated that the registration of the pharmacy into the computer readable storage medium may also be achieved, for example, by telephone and/or through the use of an integrated voice response system.

[0021] As noted above, the drug delivery methods described herein also preferably involve the registration of the patient in a computer readable storage medium. The computer readable storage medium in which the patients are registered may be the same as, or different from the computer readable storage medium in which the prescriber and/or pharmacy is registered. Generally speaking, in order to become registered in the computer readable storage medium, the patient may be required to comply with various aspects of the methods described herein. The registration of the patient may be carried out by the registered pharmacy, for example at the time of the patient's initial visit to the pharmacy. It has been found, however, that it may be more efficient, and better compliance with the methods of the present invention may be provided, if registration of the patient is carried out by the registered prescriber of the drug at the time the initial prescription is generated.

[0022] In preferred form, the prescriber will typically have a registration card or form filled out for the patient, which includes information on the patient, such as the patient's name, sex, mailing address, date of birth, and the like. Information on the prescribing prescriber and dispensing pharmacy, such as the information described above for the registration thereof, may also be desirably entered on the patient registration card or form. The completed card or form may then be forwarded to the manufacturer or distributor of the drug, or other authorized recipient of the registration form, for example, by mail, facsimile transmission or on-line transmission. Where registration is by mail or facsimile, entry of the registration into the computer readable storage medium may preferably include the use of optical character recognition (OCR) software. It is also possible that the registration of the patient into the computer readable storage medium may also be achieved, for example, by telephone and/or through the use of an integrated voice response system.

[0023] Preferably, information will also be collected from the patient that may be probative of the risk that a known or suspected side effect will occur if the drug is taken by the patient. This information may then be compared with a predefined set of risk parameters for the drug, which in turn define a plurality of risk groups, so that analysis of the information will permit assignment of the patient to at least one of the risk groups. Preferably, this risk group assignment is then also entered into the computer readable storage medium. This assignment may be performed by the prescriber, who may then include the risk group assignment on the patient's registration card or form, or may be performed by another individual, such as a nurse, technician, or office personnel, who preferably interprets the information and assigns the patient to one of the risk groups, accordingly.

[0024] As discussed above, it is preferable that a plurality of risk groups, each based upon a predefined set of risk parameters, be established for the drug which is to be administered. As will be evident to those of skill in the art, the risk parameters to be considered and the risk

groups defined by those parameters, will be based upon factors which influence the risk that a known or suspected adverse side effect will occur if the patient receives the drug, and will vary depending upon the drug in question. Where the drug is a teratogenic drug, for example, such risk parameters may include elements which would impact the risk of a foetus being exposed to the drug, such as the age, sex and reproductive status of the patient. For example, a first risk group may comprise female patients of child bearing potential; a second risk group may comprise female patients of non-child bearing potential; a third risk group may comprise sexually active male patients; and a fourth risk group may comprise sexually inactive male patients. Additionally, there may be a risk group established for patients to whom administration of the drug may be strictly contraindicated, and patients assigned to such a group will not be approved to receive the drug. For other drugs, different factors, such as those influencing the likelihood that certain preexisting conditions may exist, or the likelihood of certain other drugs being used concomitantly with the prescribed drug, may define the relevant risk parameters.

[0025] By assigning each patient to a risk group, the steps that will be taken to minimize the chance that the drug is dispensed to a contraindicated patient, and to minimize the risk that a known or suspected adverse side effect will occur, can be tailored to suit the circumstances of that particular patient. For example, depending upon which risk group a patient is assigned to, additional information may be collected from the patient. As discussed more fully below, such additional information may be in the form, for example, of a patient survey. Such additional information may also include the results of certain diagnostic tests which have been performed. Based upon the additional information, the patient's risk group assignment may then remain the same, or the patient may be assigned to a different risk group, which may in turn require that further additional information be collected from the patient.

[0026] In accordance with the present invention, the monitoring of two, three or more drugs either administered to or proposed for administration to a patient may also be accomplished in order to avoid or diminish the likelihood of the occurrence of one or more side effects. Thus, combinations of drugs which, when administered to an individual patient, may give rise to an increased likelihood of side effects, may be registered in a computer readable storage medium, and the patient's risk group assignment may be reflective of this increased risk. A physician is registered to prescribe at least one of the drugs for a patient and a pharmacy is registered to fill such prescription. In this way, through assignment of such patient to one or more risk groups, the avoidance of harmful drug interactions may be attained.

[0027] It is preferred that for any given risk group, there may be defined a predetermined additional set of information which is to be collected from the patient. This additional set of information may be obtained prior to the initial dispensation of the drug to the patient and/or may be obtained from the patient on a periodic basis. This information may include information not previously obtained from the patient, or may simply reiterate previously asked questions, and repeat diagnostic tests which were conducted previously. The information may relate to the patient's conduct, or may relate to the patient's past or ongoing medical

treatment, such as other procedures or medication which the patient may have received or is still receiving. For example, the additional set of information may be in the form of a survey or questionnaire regarding the patient's behavior and compliance with risk avoidance measures and may thus be probative of whether the risk of occurrence of an adverse side effect has increased, decreased or remained the same. Based upon the responses by the patient, the patient's risk group assignment may, if appropriate, be changed accordingly. Alternatively, where side effects which are known or suspected of being caused by a combination of drugs, the questions asked of the patient may be probative of the likelihood that the patient may take such a combination of drugs. Similarly, where sharing of drugs by the patient may be a matter of concern, the survey may be probative of the risk that the patient may be sharing the hazardous drug with another, and hence increase the risk that a contraindicated individual may receive the drug.

[0028] The additional information may also include the results of certain diagnostic tests which have been performed on the patient. Such diagnostic tests may be probative, for example, of the risk of exposure of a foetus to a teratogenic drug, may test for the presence of a risk factor for the adverse side effect of concern, or may be probative of the onset of that side effect. Where the use of combinations of more than one drug are known or suspected of causing an increased risk of the occurrence of a side effect, the diagnostic testing may include testing for the presence of one or more of those drugs, or evidence of the use by the patient of such other drugs. Additionally, diagnostic tests may be probative of the concentration of one or more drugs, including the prescribed drug or drugs, to assure that appropriate dosing is maintained.

[0029] Such diagnostic testing may be conducted on any bodily fluid or waste product of the patient, including the blood, serum, plasma, saliva, semen or urine, as well as the feces. Diagnostic testing may also be performed on a biopsy of any tissue of the patient or may include genetic testing, which may be indicative of a genetic predisposition to a particular adverse side effect. Other forms of diagnostic testing, such as diagnostic imaging, or tests which may be probative of the proper functioning of any tissue, organ or system are also contemplated. Preferably, the additional information and/or diagnostic test results are obtained and entered in the computer readable storage medium before the patient is approved to receive the drug. Additionally, where the information indicates that the risk of the adverse side effect occurring outweighs the potential benefit of the drug, the patient may be assigned to a risk group that will preclude approval of dispensation of the drug to that patient.

[0030] In accordance with the methods of the present invention, therefore, the delivery of the drug to the patient may involve the following steps. As a prelude to prescribing and dispensing the drug to the patient, the prescriber and the pharmacy are registered in one or more appropriate computer readable storage media, as described above. If the prescriber is not registered in the computer readable storage medium, the prescriber will be ineligible to prescribe the drug. Similarly, if the pharmacy is not registered in the computer readable storage medium, the pharmacy will be ineligible to dispense the drug.

[0031] In the course of an examination of a patient, including patients suffering from one or more diseases and/or disorders such as, for example, erythema nodosum leprosum (ENL), the prescriber may determine that the patient's condition would be improved by the administration of a drug such as, for example, a teratogenic drug, including thalidomide. Prior to prescribing the drug, the prescriber preferably counsels the patient, for example, on the various risks and benefits associated with the drug. For example, the prescriber preferably discusses the benefits associated with taking the drug, while also advising the patient on the various side effects associated therewith. In embodiments of the invention wherein the prescriber assigns the patient to a specific risk group, the disclosure is preferably tailored to that risk group assignment. Thus, a patient who may acquire or impart a condition or disease for which the drug is contraindicated is preferably counseled by the prescriber on the dangers associated therewith and advised as to risk avoidance measures which may be instituted. Preferably the patient is provided full disclosure of all the known and suspected risks associated with taking the drug. For example, in the case of teratogenic drugs, the prescriber preferably counsels the patient on the dangers of exposing a foetus, either one which may be carried by the patient or one carried by a recipient of the bodily fluids of the patient, to the teratogenic drug. Such counsel may be provided verbally, as well as in written form. In preferred embodiments, the prescriber provides the patient with literature materials on the drug for which a prescription is contemplated, such as product information, educational brochures, continuing education monographs, and the like. Thus, in the case of methods involving teratogenic drugs, the prescriber preferably provides patients with literature information, for example, in the form of the aforesaid product information, educational brochures, continuing education monographs, and the like, warning the patient of the effects of the drug on foetuses. In the case of other drugs which are known or suspected of causing an adverse side effect, the patient is counseled as to the dangers of taking the drugs, and of steps which may be taken to avoid those risks. For example, if the concomitant use of the drug and another drug, for example alcohol, is to be avoided, the prescriber advises the patient of the risks of drinking alcohol while taking the drug.

[0032] With particular reference to counseling provided in connection with teratogenic drugs, the prescriber preferably counsels female patients that such drugs must never be used by pregnant women. If the patient is a female of child-bearing potential (i.e., a woman who is capable of becoming pregnant), the prescriber preferably counsels the patient that even a single dosage of certain teratogenic drugs, such as thalidomide, may cause birth defects. Accordingly, the patient is preferably counseled to avoid sexual intercourse entirely, or if sexually active, to use appropriate forms of contraception or birth control. For both male and female patients, the prescriber preferably provides counsel on the importance of using at least two forms of effective birth control methods, with one form preferably being a highly effective hormonal method, and the other form preferably being an effective barrier method. The patients are preferably counseled to use the birth control methods for a period of time prior to and during treatment with the teratogenic drug, as well as for a period of time after treatment with the drug has been

terminated. In preferred embodiments, the patient is counseled to use at least two forms of birth control for at least about 4 weeks prior to initiation of treatment, during treatment, and for at least about 4 weeks after treatment has been terminated. It may be desirable for the prescriber to personally provide female patients who are capable of becoming pregnant with one or more contraceptive devices or formulations.

[0033] Male patients who are being prescribed a teratogenic drug are preferably counseled to use condoms every time they engage in sexual relations, since many teratogenic drugs may be found in semen. Male patients are also preferably counseled to contact their prescriber if they have sexual intercourse without a condom, and/or if it is believed that they may have caused a pregnancy. As with female patients, it may be desirable for the prescriber to provide male patients who are capable of impregnating female patients with a contraceptive device or formulation. Other advice relative to birth control that the prescriber may provide to the patient would be apparent to one skilled in the art, once armed with the teachings of the present application. If the prescriber who is prescribing the teratogenic drug is unaware of certain aspects of the available forms of birth control and the advantages and disadvantages associated therewith, the patient should be referred to a prescriber who is knowledgeable on such matters, prior to be being prescribed the involved drug. Generally speaking, as discussed below, counseling on teratogenecity, birth control, and the like is preferably given only to female patients who are capable of becoming pregnant, or to male patients who are capable of having sexual relations with partners who are or can become pregnant. In this manner, unnecessary counseling, for example, to women who are no longer of child-bearing age or men who are incapable of sexual relations with such women, may be avoided.

[0034] With further reference to methods involving teratogenic drugs, it is also preferred that the prescriber advise the patient to not share the drug with anyone else, and particularly that the drug should be kept out of the reach of children as well as women of child-bearing potential. In the case of female patients, particularly female patients of child-bearing potential, the prescriber should give the patient a pregnancy test, preferably a serum pregnancy test, prior to and during treatment with the teratogenic drug. To begin receiving the teratogenic drug and to continue taking the drug, female patients of child-bearing potential should continue to have negative pregnancy tests. The patient is also preferably counseled by the prescriber to discard or return to the prescriber, pharmacy, manufacturer or distributor any unused portion of the prescribed drug.

[0035] As would be apparent to one of ordinary skill in the art, once armed with the teachings of the present application, one or more aspects of the counseling described above may be applicable, in certain circumstances, for drugs other than teratogenic drugs.

[0036] In addition to receiving counseling on the drug being prescribed, including counseling, for example, on birth control, and prior to receiving a prescription for the drug, the methods of the present invention preferably involve requiring the patient to fill out an informed consent form which is signed by the prescriber, as well as the patient. The prescriber should

retain a copy of the informed consent form for his/her records. Verification that the patient has given his/her informed consent may also be registered in the computer readable storage medium. Preferably, this verification is provided by the prescriber, and may be included, for example, with the patient registration information and risk group assignment. It has surprisingly been found that by having the prescriber, rather than the pharmacy, verify the patient's informed consent, the methods of the present invention may operate more efficiently, leading to better compliance, and hence decreased risk that the adverse side effect will occur, may be achieved.

[0037] By filling out and signing an informed consent form, the patient acknowledges that he/she understands the risks associated with taking the drug. In the informed consent form, the patient preferably agrees to comply with the risk avoidance measures provided, and to behave in a manner which is consistent with the prescriber's counsel. For example, in cases involving, for example, teratogenic drugs, the patient may agree to use at least one form of birth control, with female patients agreeing to use at least two forms of birth control. In preferred embodiments, where the patient's risk group assignment so dictates, the patient will agree to undergo periodic diagnostic testing relevant to the risk that the adverse side effect to be avoided may occur or be occurring. In preferred embodiments involving teratogenic drugs, female patients preferably agree also to undergo pregnancy testing, preferably serum pregnancy testing, before, during and after treatment with the teratogenic drug. Female patients preferably will also acknowledge that, at the time they are being prescribed the drug, especially teratogenic drugs, they are not pregnant, they will immediately stop taking the drug if they become pregnant, and they will not try to become pregnant for at least 4 weeks after treatment with the drug is terminated. Female patients, especially female patients for whom a teratogenic drug will be administered, preferably further agree to contact their prescriber if they wish to change one or more of the birth control methods being used and to have an additional pregnancy test if a menstrual period is missed. Female patients, especially female patients to be treated with teratogenic drugs, will preferably agree also to not breast-feed while being treated with the drug.

[0038] Male patients who are being prescribed the drugs according to the methods described herein, especially teratogenic drugs, will preferably agree to avoid having unprotected sexual relations with a woman, particularly a woman of child-bearing potential during treatment with the drug. In doing so, male patients will preferably further agree to use a condom during sexual relations with a woman, with latex condoms being preferred. Both male and female patients will also preferably agree to not share the drug with anyone, and to acknowledge that they cannot donate blood while taking the drug, with male patients agreeing also to not donate sperm while taking the drug. In addition, the patients will preferably agree to take part in a confidential patient survey, for example, before, during and after treatment with the drug. The patient survey provides information, for example, to the prescriber, manufacturer and/or distributor of the drug, as well as any group or body which may be established to generally provide oversight on the distribution of the drug, on information regarding the general lifestyle of the patient, including detailed information on the patient's sexual behavior. In this manner,

the survey may assist in identifying patients who engage in risky behavior, as well as patients who are non-compliant with the methods described herein. Such risky behavior and/or non-compliance may lead to a suspension or intervention of the patient's treatment with the drug, with re-education being provided to the patient.

[0039] The information obtained from the survey is preferably also entered into the computer readable storage medium. Once entered into the computer readable storage medium, the prescriber, manufacturer and/or distributor of the drug may be able to glean therefrom information regarding the level of risk associated with the administration of the involved drug to the various patients. Accordingly, it may be possible to identify, from among the entire population of registered patients, one or more subpopulations of patients for which the involved drug may be more likely to be contraindicated. For example, it may be possible to identify a subpopulation of female patients who are capable of becoming pregnant and/or a subpopulation of male patients who are capable of impregnating female patients. Preferably, the counseling information discussed above relating to exposure of a foetus to a teratogenic drug may then be addressed primarily to this subpopulation of patients.

[0040] If the risk is considered to be acceptable, the patient may continue to receive the drug, using the methods described herein. If the risk is considered to be unacceptable, additional counseling may be provided to the patient or, if necessary, treatment of the patient with the involved drug may be terminated, with alternate treatment modalities being provided. In preferred embodiments, female patients will agree to complete a patient survey at least once every month, with male patients agreeing to complete a patient survey at least once every three to six months. The survey may be conducted by mail, facsimile transmission, on-line transmission or by telephone. Preferably, the survey is conducted by telephone through the use of an integrated voice response system (IVR).

[0041] After the patient has received counseling as described above, and has also filled out and signed an informed consent form, and it is determined that the drug which is to be prescribed is not contraindicated for the patient (such as, for example, a negative pregnancy test in the case of female patients for whom a prescription is desired for a teratogenic drug), the prescriber may prescribe the drug to the patient. In preferred embodiments of the present invention, the amount of the drug which is prescribed to the patient is for a limited amount, preferably no more than about 28 days. Refills for the drug will not be permitted without a renewal prescription from the prescriber, as discussed in detail below. In order to have the prescription filled, the patient preferably presents the prescription and the informed consent form to a pharmacy who has been registered, as discussed above. It is contemplated that the patient may bring the prescription to an unregistered pharmacy. If so, the pharmacy may take steps to become registered, for example, by immediately contacting the manufacturer of the drug. Once registration of the pharmacy is completed, the distribution procedure described herein may resume, per the discussion hereinafter. Of course, this may introduce a delay into the prescription process, and the patient may desire to take the prescription for the drug to an

alternate, registered pharmacy. If the patient does not present a completed informed consent form to the pharmacy, or if verification of such informed consent has not previously been registered in the computer readable storage medium, the prescription may not be filled. In this case, pharmacy may contact the prescribing prescriber to have an informed consent form filled out for the patient.

[0042] The drug is preferably supplied to the pharmacy (as well as the patient) in packaging, such as individual blister packs, which includes warnings regarding the risks associated with the drug, as well as the importance of various aspects of the present methods such as, for example, pregnancy testing and the use of contraception (in the case of teratogenic drugs), and the dangers associated with sharing the drug with others, among other aspects.

[0043] As noted above, the drug is preferably prescribed and dispensed to the patient in a limited amount, with a prescription amount of no more than about 28 days being preferred, and preferably with no refills being permitted. Thus, for the patient to obtain an additional prescription, it is generally necessary for the patient to have a follow-up visit with the prescriber. Such a follow-up visit preferably takes place at least each time the patient requires a renewal of the prescription, and possibly more often if the patient requires, for example, additional counseling. At the follow-up visit, the patient will preferably receive additional counseling regarding the risks and benefits associated with taking the drug, as well as further counseling on birth control (if applicable). The patient will also preferably complete an additional patient survey to provide current information regarding their lifestyle, including their sexual behavior and, if female of childbearing potential, be administered a new pregnancy test. After receiving the counseling and completing the patient survey, and if the pregnancy tests for female patients are negative, the prescriber may fill out a new prescription for the drug. As with the original prescription, the renewal prescription is preferably for a limited period of time, with no more than about 28 days being more preferred.

[0044] In certain embodiments, the prescriber may also receive reminders, for example, via mail, facsimile, or on-line transmission, from the manufacturer, distributor or other group or body providing oversight on drug distribution, that the prescriber has prescribed a hazardous drug to patients which may be contraindicated, and that the involved patients may require additional counseling and diagnostic testing. Such reminders may preferably be delivered to the prescriber, for example, from about 14 to about 21 days after the previous prescription was filled.

[0045] As with the original prescription from the prescriber, the patient should present all renewal prescriptions to a registered pharmacy. Prior to filling out the prescription and dispensing the drug, the pharmacy preferably confirms, for example, via a standard on-line transmission or via telephone via IVR that the patient has been registered and is eligible to receive the drug. When patient eligibility has been confirmed, the pharmacy may dispense the drug to the patient. If the patient is ineligible, the pharmacy generally may not dispense the drug to the patient. The pharmacy may then contact, for example, the prescribing prescriber or the manufacturer of the drug to initiate patient registration. In preferred form, the pharmacy will be

precluded from dispensing the drug if the patient has more than about 7 days of drug supply from the previous prescription, and/or if the new prescription was written more than about 14 days before the date the patient visits the pharmacy to have it filled.

[0046] The registration into one or more computer readable storage media of the prescriber, pharmacy and patient, according to the methods described herein, provide a means to monitor and authorize distribution of contraindicated drugs, including teratogenic drugs. Thus, the computer readable storage media may serve to deny access to, dispensing of, or prescriptions for contraindicated drugs, including teratogenic drugs, to patients, pharmacies or prescribers who fail to abide by the methods of the present invention. As noted above, prescribers who are not registered in a computer readable storage medium generally may not prescribe the drug, and pharmacys who are not registered generally may not dispense the drug. Similarly, the drugs generally may not be prescribed and/or dispensed to patients who are not registered in a computer readable storage medium. In addition, patients may be required to present an informed consent form to the pharmacy. Unless such a form is presented to the pharmacy, or verification of such informed consent has been provided by the prescriber and registered in the computer readable media, the patient generally may not receive the prescription for the drug. As noted above, only limited amounts of the drug may be prescribed to the patient, with no refill prescriptions being permitted.

[0047] In certain embodiments of the invention, the methods may require that the registered pharmacy consult the computer readable medium to retrieve a prescription approval code before dispensing the drug to the patient. This approval code is preferably not provided unless the prescriber, the pharmacy, the patient, the patient's risk group and the patient's informed consent have been properly registered in the storage medium. Additionally, depending upon the risk group assignment, generation of the prescription approval code may further require the registration in the storage medium of the additional set of information, including periodic surveys and the results of diagnostic tests, as have been defined as being relevant to the risk group assignment. Thus, to comply with the present methods and receive approval to dispense the drug as prescribed, the registered pharmacy need only retrieve the approval code. If the prescription approval code is not forthcoming, the patient may be directed to complete the necessary survey, for example, by telephone, or may be directed back to the prescriber for completion of necessary diagnostic tests. In this manner, the effort required by the pharmacy is minimized, and greater compliance with the present methods may efficiently and advantageously be achieved. Additionally, the embodiments described herein may provide greater assurance that all required further information, as is appropriate to the patient's risk group assignment, has been obtained before the drug is dispensed to the patient, and thereby minimize the risk that an adverse side effect will occur.

[0048] While the delivery of teratogenic drugs is an aspect of the present invention which has clearly apparent benefit, other types of drugs may also beneficially be prescribed and delivered in accordance with one or more embodiments hereof and all are contemplated hereby.

For example, the methods of the present invention may be used for delivery of a drug which is known or suspected of causing liver damage in many patients who take the drug. One such drug is isoniazid, a widely known treatment for tuburculosis (TB). In following a method of the present invention, a registered physician may wish to prescribe isoniazid to a patient who has tested positive for TB. The physician may register the patient in a computer readable storage medium, along with certain information regarding the patient's age, medical condition, and so on. If the patient is a young adult, for example, and presents with no other complicating risk factors, the patient may be assigned to a risk group that is designated to receive counseling regarding certain behavior, such as the concomitant use of alcohol, that is to be avoided. The patient may be fully informed of the risks of liver damage that may result from taking isoniazid, and is preferably counseled to avoid drinking any alcoholic beverages while undergoing treatment with the drug. Preferably, the patient signs an informed consent form, and the prescribing physician transmits verification of the informed consent, along with the patient's registration form and risk group assignment to the computer readable storage medium. The physician then provides the patient with a prescription for the isoniazid. Upon presentation of the prescription to a registered pharmacy, the computer readable storage medium is consulted to verify that the patient and prescriber are registered therein, and that the patient's risk group assignment and informed consent have been provided.

[0049] If the patient's risk group assignment so indicates, certain diagnostic tests may additionally be required, so that baseline data may be obtained, before the prescription will be approved for filling. The patient's risk group may indicate, for example, that serum liver enzymes should be evaluated on a monthly basis. Under these circumstances, the prescription will preferably be filled for no more than about 30 days.

[0050] The patient will also preferably be advised that completion of a monthly survey will be required. This survey may include a questionnaire which is probative of the patient's alcohol consumption over the past month. The survey may also include questions which are probative of certain symptoms which may be indicative of the early onset of liver damage or other side effects known or suspected of being caused by isoniazid. Additionally, questions regarding the patient's concomitant use of other drugs which are known to be hazardous when taken in combination with isoniazid. may be asked. Preferably, this survey is conducted telephonically, using an integrated voice response system, and the responses are entered in the storage medium. Based upon the patient's responses, the patient's risk group assignment is adjusted or left the same, as may be appropriate.

[0051] The patient is preferably further instructed that periodic diagnostic testing may also be necessary for continued approval of a prescription. Preferably, the diagnostic testing will include an assay of the patient's serum liver enzyme levels, to screen for early signs of liver damage. Additionally, the diagnostic testing may include screens for the presence of other drugs known to also cause liver damage, or to be hazardous if taken in combination with isoniazid. A prescription approval code generally will not be generated for subsequent prescriptions or refills

until such periodic tests have been performed and satisfactory results entered into the computer readable storage medium. If a prescription approval code is not received by the pharmacy, the patient is directed to complete the requisite survey or tests, or to return to the doctor for further consultation.

[0052] If the test results or survey indicate that the risk of liver damage has increased, the patient's risk group assignment may be changed, or the patient will be directed to consult with the prescriber before any further isoniazid may be dispensed. In this way, the development of the adverse side effect of concern may be monitored. For example, if the tests indicate that some liver enzymes are marginally elevated, the patient's risk group status may be changed from a first risk group to a second risk group. As a member of this second risk group, the patient may be required to undergo additional diagnostic testing before approval will be given to receive the drug. Such testing may include, for example, liver function tests, to further diagnose the level of cellular damage potentially being caused by the isoniazid, or the combination of isoniazid and other drugs, such as alcohol. In more extreme cases, a diagnostic ultrasound of the liver, or even a liver biopsy may even be indicated. Ultimately, if the risk of continued administration becomes so great that it outweighs the possible benefits of continued treatment with isoniazid, the patient may be assigned to a risk group which indicates that the drug may no longer be dispensed to that patient.

[0053] The methods of the present invention may similarly be employed, for example, where the patient is undergoing treatment for infection with the Human Immunodeficiency Virus (HIV). Patients who test positive for HIV may be treated with one or more drugs to combat the onset of the Acquired Immune Deficiency Syndrome (AIDS). Frequently, HIV positive patients are administered an "AIDS cocktail" of several drugs including, for example, a combination of one or more inhibitors of viral protease and reverse transcriptase. By following the methods of the present invention, the patient may continue to receive the combination of drugs, while the risk of adverse side effects from administration of the drugs may be minimized. Additionally, the methods of the present invention may be desirably and advantageously used to educate and reinforce the actions and behaviors of patients who are taking a drug, as well as prescribers who prescribe the drug and pharmacies which dispense the drug.

[0054] As with methods of the invention previously described, when a patient has tested positive for HIV, a registered prescriber may obtain background information on the patient and see that a registration form is completed so that the patient may be registered in the computer readable storage medium. The prescriber may prescribe one or more drugs to the patient, including drugs which may be known or suspected of causing adverse side effects, either alone or in combination with each other or with other drugs. Depending upon the drugs prescribed, and also upon information which the prescriber will preferably obtain regarding the patient's medical history, physical condition and lifestyle, the patient will preferably be assigned to at least one risk group. Based upon this risk group assignment, the patient will preferably receive educational materials and counseling regarding the risks associated with the prescribed drugs,

and be advised of the importance of the treatment regimen. The patient will also preferably receive counseling regarding the risk of spreading the disease to others, including a foetus which may be carried by the patient and any recipient of a bodily fluid of the patient. Thus, the patient may be counseled regarding the preferential use of one or more methods of birth control, and may also be provided with a contraceptive device by the prescriber. Additionally, the patient will preferably be counseled not to share any of the drugs with others, and to avoid taking any medications not prescribed. In this way, the patient will preferably be counseled both as to methods for minimizing the spread of the disease, as well as to methods for avoiding the occurrence of one or more side effects which may result from the taking of the medication. Preferably, upon full disclosure of all risks inherent in the treatment regimen, the prescriber will obtain and register in the computer readable storage medium the informed consent of the patient to receive the medication and to comply with the methods described herein for avoiding the occurrence of one or more side effects which may result from taking the drug or drugs prescribed.

[0055] To facilitate compliance with the methods of the present invention, and to minimize the likelihood of the occurrence of a known or suspected adverse side effect from treatment with the prescribed drug or drugs, it is preferable that when prescriptions for the drug are presented to a registered pharmacy, the computer readable storage medium is consulted to retrieve a prescription approval code before the drug is dispensed to the patient. In order for a prescription approval code to be generated, and based upon the patient's risk group assignment, the patient may be required to provide additional information, which may then be entered in the storage medium before approval of the prescription may be provided. For example, the patient may be required to undergo certain diagnostic tests. In a patient with HIV, for example, testing for viral load may be required, both initially and on a periodic basis, so that dosing of the medication may be adjusted, as necessary. The patient may also be required to complete a survey which asks questions probative of the likelihood that the patient is taking other medications, or beginning to exhibit symptoms which may be of importance to the selection and implementation of a therapeutic regimen. Such additional information may be required both before the initiation of treatment and on a periodic basis during treatment, as new prescriptions and prescription refills are generated. Based upon the information provided by the patient, and the results of any diagnostic tests which have been performed, the patient's risk group assignment may stay the same, or may be changed, as indicated. The patient's risk group assignment may also be changed based upon the length of time the patient has been receiving a given drug or medication.

[0056] A periodic patient survey may serve both to remind the patient of the requirements of the drug distribution program, and to obtain information which may be probative of the risk that an adverse side effect may occur. For example, the survey may include questions probative of the patient's behavior as it relates to the sharing of medication with other HIV positive individuals, and the patient's compliance with measures for avoiding the spread of the

disease. Additionally, the survey may include questions regarding other drugs, medications or treatments which the patient might be availing themselves of, which would impact the risk of an adverse side effect occurring.

[0057] The survey may also contain questions which are probative of the onset of certain symptoms which may be indicative of the need for changes in the patient's treatment regimen. For example, some questions may be probative of the onset of depression in the patient, a common occurrence amongst AIDS sufferers. Answers to questions in the survey that are indicative of depression, for example, may cause the patient's risk group assignment to change such that the patient is directed to return to the prescriber for determination of whether treatment with an anti-depressant drug is indicated. Similarly, certain drugs, such as protease inhibitors, for example, may lead to abnormal redistribution of fat in certain patients. This symptom may be seen in conjunction with certain metabolic defects and may in turn be symptomatic of conditions such as high blood sugar and high cholesterol. Questions relating to this abnormality may be included on the survey, and answers which indicate that the patient has noticed such physical changes may lead to the assignment of the patient to a risk group in which diagnostic tests probative of the metabolic abnormalities are required before further access to the drug in question is permitted.

[0058] As with the survey, the diagnostic testing which the patient may be required to undergo may vary with, and preferably is appropriate to, the patient's risk group assignment. In addition to testing for the patient's viral load, periodic diagnostic testing may be appropriate, for example, to evaluate the level of one or more medications in the patient. Dosage of reverse transcriptase inhibitors, for example, may be critical to the risk of occurrence of an adverse side effect. At the same time, various drugs which are often used in combination may share similar metabolic pathways, so that the addition of a second drug to the treatment regimen may greatly affect the pharmacokinetics of the first drug, thereby necessitating an adjustment in the dose of the first drug. In the case of treatment with an "AIDS cocktail" containing, for example, the use of ritonavir, a well-known protease inhibitor, may greatly impact the bioavailability of other protease inhibitors, requiring that the dose of the other protease inhibitors be reduced. Accordingly, the inclusion of ritonavir in the patient's treatment regimen may initiate a change in risk-group assignment, which in turn requires that diagnostic testing to evaluate the blood levels of other concomitantly administered protease inhibitors be done on a periodic basis.

[0059] Similarly, the addition of other drugs to the treatment regimen, either by the prescribing physician, or by another physician whom the patient might visit, may interfere with the initial treatment regimen prescribed by the registered prescriber. For example, AIDS patients often develop mycobacterial infections such as tuberculosis. An infectious disease specialist may prescribe one of a class of drugs known as rifamycins, such as rifampin or rifabutin, to treat such infections. Rifamycins are known to accelerate the metabolism of many protease inhibitors, however, so that upon initiation of treatment with a rifamycin, the effectiveness of the protease inhibitors may be greatly reduced, unless the dosage of those drugs

is adjusted appropriately. Thus, when the patient is being treated with a protease inhibitor, the survey may include, for example, questions regarding the possible concurrent use of a rifamycin. If the survey results indicate that the two types of drugs are being used concurrently, the patient's risk group assignment is changed, such that the patient may be referred back to the prescriber for an adjustment in dosage, or the patient may be directed to undergo diagnostic testing to assure that a sufficient level of the protease inhibitor is still being maintained. Similarly, where the registered prescriber adds a prescription for a rifamycin to the treatment regimen of a registered patient who is also receiving a protease inhibitor, entry of the prescription into the computer readable storage medium may trigger an automatic change in risk group assignment, such that approval of the prescription will not be generated without further modification of the dosage of the protease inhibitor. In this way, the methods of the present invention may be advantageously utilized to maintain the proper dosing of one or more drugs, to minimize the likelihood of the occurrence of an adverse side effect from the concomitant use of such drugs, or the addition of other drugs to a treatment regimen, to encourage proper disclosure of the risks associated with the taking of one or more drugs, to minimize the risk that a contraindicated individual will be exposed to the potentially hazardous drugs, and to assist in generating patient compliance with treatment protocols and avoidance of behavior known to increase the risk that the disease will be spread to others.

[0060] Various modifications of the invention, in addition to those described herein, will be apparent to those skilled in the art from the foregoing description. Such modifications are also intended to fall within the scope of the appended claims.

What is Claimed:

1. A method for treating erythema nodosum leprosum using thalidomide while restricting access to thalidomide for patients for whom thalidomide may be contraindicated, said method comprising permitting prescriptions for thalidomide to be filled by a pharmacy only after the pharmacy has received an approval code for the prescription from a computer readable storage medium, wherein generation of the prescription approval code comprises the following steps:

a. defining a plurality of patient risk groups based upon a predefined set of risk parameters for thalidomide;

b. defining a set of information to be obtained from the patient, which information is probative of the risk that an adverse side effect is likely to occur if thalidomide is taken by the patient;

c. in response to the information set, assigning the patient to at least one of the risk groups and entering the patient, the information and the patient's risk group assignment into the medium;

d. based upon the information and the risk group assignment, determining whether the risk that the adverse side effect is likely to occur is acceptable; and

e. upon a determination that the risk is acceptable, generating the prescription approval code to be received by the pharmacy before the prescription is filled.

2. A method according to claim 1 further comprising registering in the medium the physician who prescribed the drug.

3. A method according to claim 1 further comprising registering the pharmacy in the medium.

4. The method of claim 1 further comprising counseling the patient as to the risks of taking the drug and advising the patient as to risk avoidance measures, in response to the risk group assignment.

5. The method of claim 4 wherein the counseling comprises full disclosure of the risks.

6. The method of claim 5 wherein the prescription is filled only following the full disclosure and informed consent of the patient.

7. The method of claim 6 wherein the informed consent is registered in the computer readable storage medium prior to generation of the prescription approval code.

8. The method of claim 7 wherein the risk group assignment and the informed consent is transmitted to the computer readable storage medium by facsimile and interpreted by optical character recognition software.

9. The method of claim 1 further comprising:

f. defining for each risk group a second set of information to be collected from the patient at periodic intervals;

g. obtaining the second set of information from the patient; and

h. entering the second set of information in the medium.

10. A method for treating a patient having a disease or condition which is responsive to thalidomide while restricting access to thalidomide for patients for whom thalidomide may be contraindicated, the method comprising permitting prescriptions for thalidomide to be filled by a pharmacy only after the pharmacy has become aware of approval of a prescription for thalidomide for the patient from a computer readable storage medium, the generation of the prescription approval comprising the following steps:

a. defining a plurality of patient risk groups based upon a predefined set of risk parameters for thalidomide;

b. defining a set of information to be obtained from the patient, which information is probative of the risk that an adverse side effect is likely to occur if thalidomide is taken by the patient;

c. in response to the information set, assigning the patient to at least one of the risk groups and entering the patient, the information and the patient's risk group assignment into the medium;

d. based upon the information and the risk group assignment, determining whether the risk that the adverse side effect is likely to occur is acceptable; and

e. upon a determination that the risk is acceptable, generating the prescription approval before the prescription is filled.

11. A method according to claim 10 further comprising registering in the medium the physician who prescribed the drug.

12. A method according to claim 10 further comprising registering the pharmacy in the medium.

13. The method of claim 10 further comprising counseling the patient as to the risks of taking the drug and advising the patient as to risk avoidance measures, in response to the risk group assignment.

14. The method of claim 13 wherein the counseling comprises full disclosure of the risks.

15. The method of claim 14 wherein the prescription is filled only following the full disclosure and informed consent of the patient.

16. The method of claim 15 wherein the informed consent is registered in the computer readable storage medium prior to generation of the prescription approval code.

17. The method of claim 16 wherein the risk group assignment and the informed consent is transmitted to the computer readable storage medium by facsimile and interpreted by optical character recognition software.

18. The method of claim 10 further comprising:

f. defining for each risk group a second set of information to be collected from the patient at periodic intervals;

g. obtaining the second set of information from the patient; and

h. entering the second set of information in the medium.

19. A method for treating a disease with a drug known or suspected of having teratogenic properties while restricting access to the drug by patients for whom the drug may be contraindicated the method comprising permitting prescriptions for thalidomide to be filled by a pharmacy only after the pharmacy has become aware of approval of a prescription for thalidomide for the patient from a computer readable storage medium, the generation of the prescription approval comprising the following steps:

a. defining a plurality of patient risk groups based upon a predefined set of risk parameters for thalidomide;

b. defining a set of information to be obtained from the patient, which information is probative of the risk that an adverse side effect is likely to occur if thalidomide is taken by the patient;

c. in response to the information set, assigning the patient to at least one of the risk groups and entering the patient, the information and the patient's risk group assignment into the medium;

d. based upon the information and the risk group assignment, determining whether the risk that the adverse side effect is likely to occur is acceptable; and

e. upon a determination that the risk is acceptable, generating the prescription approval before the prescription is filled.

ABSTRACT

Methods for delivering a drug to a patients in need of the drug, while restricting access to the drug by patients for whom the drug may be contraindicated are disclosed. The methods are of the type in which prescriptions for the drug are filled by a pharmacy only after a computer readable storage medium has been consulted to retrieve a prescription approval code. Embodiments are provided wherein the patients are assigned to risk groups based upon the risk that taking the drug will lead to an adverse side effect, and certain additional information, such as periodic surveys and diagnostic tests probative of the ongoing risk of the side effect developing are obtained before prescriptions for the drug are approved.

DOCKET NO. CELG-0188 PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of:

Bruce A. Williams and Joseph K. Kaminski

Group Art Unit: Not assigned

For: METHODS FOR DELIVERING A DRUG TO A PATIENT WHILE AVOIDING THE OCCURRENCE OF AN ADVERSE SIDE EFFECT KNOWN OR SUSPECTED OF BEING CAUSED BY THE DRUG

Examiner: Not assigned

DECLARATION AND POWER OF ATTORNEY

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name; and

I believe that I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a

☒ Utility Patent ☐ Design Patent

is sought on the invention, whose title appears above, the specification of which:

☒ is attached hereto.

☐ was filed on _____ as Serial No. _____ .

☐ said application having been amended on _____ .

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose to the U.S. Patent and Trademark Office all information known to be material to the patentability of this application in accordance with 37 CFR § 1.56.

I hereby claim foreign priority benefits under 35 U.S.C. § 119(a-d) of any **foreign application(s)** for patent or inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of

any application on which priority is claimed:

Priority Claimed (If X'd)	Country	Serial Number	Date Filed
☐	_____	_____	_____
☐	_____	_____	_____
☐	_____	_____	_____
☐	_____	_____	_____

I hereby claim the benefit under 35 U.S.C. § 120 of any United States application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of 35 U.S.C. § 112, I acknowledge the duty to disclose to the U.S. Patent and Trademark Office all information known to be material to patentability as defined in 37 CFR § 1.56 which became available between the filing date of the prior application and the national or PCT international filing date of this application:

Serial Number	Date Filed	Patented/Pending/Abandoned
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____

I hereby claim the benefit under 35 U.S.C. § 119(e) of any United States provisional application(s) listed below:

Serial Number	Date Filed
_____	_____
_____	_____

I hereby appoint the following persons of the firm of **WOODCOCK WASHBURN KURTZ MACKIEWICZ & NORRIS LLP**, One Liberty Place - 46th Floor, Philadelphia, Pennsylvania 19103 as attorney(s) and/or agent(s) to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith:

John W. Caldwell	Reg. No. 28,937
David A. Cherry	Reg. No. 35,099
S. Maurice Valla	Reg. No. 43,966

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I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Name: Bruce A. Williams	Signature
Mailing Address: 37 Winding Way Flemington, NJ 08822	**Date of Signature:** 10/16/00
City/State of Actual Residence: Flemington, New Jersey	**Citizenship:** United States

Name: Joseph K. Kaminski	Joseph K Kaminski **Signature**
Mailing Address: 20 Kaylan Farm Road (KHLAN) Hampton, NJ 08827	**Date of Signature:** 10/18/00
City/State of Actual Residence: Hampton, New Jersey	**Citizenship:** United States

Name:	**Signature**
Mailing Address:	**Date of Signature:**
City/State of Actual Residence:	**Citizenship:**

Name:	**Signature**
Mailing Address:	**Date of Signature:**
City/State of Actual Residence:	**Citizenship:**

PATENT APPLICATION SERIAL NO. _____

U.S. DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICE
FEE RECORD SHEET

05/24/2006 EHAILE1 00000055 11437551

01 FC:1011	300.00	OP
02 FC:1111	500.00	OP
03 FC:1311	200.00	OP

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PATENT APPLICATION FEE DETERMINATION RECORD

Substitute for Form PTO-875 Effective December 8, 2004

Application or Docket Number: 1143.7551

APPLICATION AS FILED – PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA	SMALL ENTITY RATE ($)	SMALL ENTITY FEE ($)	OR	OTHER THAN SMALL ENTITY RATE ($)	OTHER THAN SMALL ENTITY FEE ($)
BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A	150.00		N/A	300.00
SEARCH FEE (37 CFR 1.16(k), (l), or (m))	N/A	N/A	N/A	$250		N/A	$500
EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A	$100		N/A	$200
TOTAL CLAIMS (37 CFR 1.16(i))	11 minus 20 = *		X$ 25 =		OR	X$50 =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	1 minus 3 = *		X100 =			X200 =	
APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $250 ($125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).						
MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))			+180=			+360=	
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL			TOTAL	1000

APPLICATION AS AMENDED – PART II

		(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	SMALL ENTITY RATE ($)	SMALL ENTITY ADDITIONAL FEE ($)	OR	OTHER THAN SMALL ENTITY RATE ($)	OTHER THAN SMALL ENTITY ADDITIONAL FEE ($)
AMENDMENT A	Total (37 CFR 1.16(i))	*	Minus	**	=	X$ 25 =		OR	X$50 =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=	X100 =		OR	X200 =	
	Application Size Fee (37 CFR 1.16(s))									
	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))					+180=		OR	+360=	
						TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	

		(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	SMALL ENTITY RATE ($)	SMALL ENTITY ADDITIONAL FEE ($)	OR	OTHER THAN SMALL ENTITY RATE ($)	OTHER THAN SMALL ENTITY ADDITIONAL FEE ($)
AMENDMENT B	Total (37 CFR 1.16(i))	*	Minus	**	=	X$ 25 =		OR	X$50 =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=	X100 =		OR	X200 =	
	Application Size Fee (37 CFR 1.16(s))									
	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))					+180=		OR	+360=	
						TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".
*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".
The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.

This collection of information is required by 37 CFR 1.16. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

DOCKET NO.: CELG-0508 **PATENT**
Application No.: Not yet assigned
Preliminary Amendment - First Action Not Yet Received

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:
Bruce A. Williams and Joseph K. Kaminski

Confirmation No.: **Not yet assigned**

Application No.: **Not yet assigned**

Group Art Unit: **Not yet assigned**

Filing Date: **May 19, 2006**

Examiner: **Not yet assigned**

For: **Methods for Delivering a Drug To A Patient While Restricting Access To The Drug By Patients For Whom the Drug May Be Contraindicated**

DATE OF DEPOSIT: May 19, 2006

I HEREBY CERTIFY THAT THIS PAPER IS BEING DEPOSITED WITH THE UNITED STATES POSTAL SERVICE AS FIRST CLASS MAIL, POSTAGE PREPAID, ON THE DATE INDICATED ABOVE AND IS ADDRESSED TO THE COMMISSIONER FOR PATENTS, P.O. BOX 1450, ALEXANDRIA, VA 22313-1450.

Angela Verrecchio

TYPED NAME: Angela Verrecchio
REGISTRATION NO.: 54,510

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

PRELIMINARY AMENDMENT PURSUANT TO 37 CFR § 1.115

Preliminary to examination of the above-captioned patent application, please amend the application as follows:

☒ **Amendments to the Specification** begin on page 2 of this paper.

☒ **Amendments to the Claims** are reflected in the listing of the claims which begins on page 3 of this paper.

☐ **Amendments to the Drawings** begin on page of this paper and include an attached replacement sheet.

☒ **Remarks** begin on page 6 of this paper.

DOCKET NO.: CELG-0508 **PATENT**
Application No.: Not yet assigned
Preliminary Amendment - First Action Not Yet Received

Amendments to the Specification:

On page 1, please delete the paragraph immediately after "CROSS REFERENCE TO RELATED APPLICATIONS" and replace with the following:

This application is a continuation of U.S. Application Serial No. 11/028,144, filed January 3, 2005, which is a continuation of U.S. Application Serial No. 10/762,880, filed January 22, 2004, now U.S. Patent No. 6,869,399, which is a continuation of U.S. Application Serial No. 10/383,275, filed March 7, 2003, now U.S. Pat. No. 6,755,784, which is a continuation of U.S. Application Serial No. 09/965,155, filed September 27, 2001, now U.S. Pat. No. 6,561,977, which is a continuation of U.S. Application No. 09/694,217, filed October 23, 2000, now U.S. Pat. No. 6,315,720, the entirety of each of which is hereby incorporated by reference.

This listing of claims will replace all prior versions, and listings, of claims in the application.

Listing of Claims:

Please delete claims 1-19 and add claims 20-30 as presented below:

20. (New) A method of distributing a drug, comprising:

a. receiving data from a prescriber for the drug, said data comprising information identifying a patient, the drug, and the prescriber;

b. entering the data into a computer database;

c. confirming the ability of the prescriber to prescribe the drug;

d. confirming that patient educational materials have been read;

e. generating periodic reports regarding distribution of the drug via the computer database; and

f. generating a prescription approval code for the drug comprising the following steps:

(i). defining a plurality of patient risk groups based upon a predefined set of risk parameters for the drug;

(ii). defining a set of information to be obtained from the patient, said set of information comprising the result of a determination of the ability of the patient to become pregnant and optionally comprising a determination that the patient is either (1) not currently pregnant or (2) currently pregnant;

(iii). in response to said information set, assigning the patient to at least one of said risk groups and entering the patient, the information and the patient's risk group assignment into the database;

(iv). based upon the information and the risk group assignment, determining whether the risk that an adverse side effect is likely to occur is acceptable; and

(v). upon a determination that the risk is acceptable, generating the prescription approval code before a prescription is filled.

21. (New) The method of claim 20, further comprising the step of recording the confirmation that the educational materials have been read in the database.

22. (New) The method of claim 20, further comprising the step of blocking inappropriate refill requests.

23. (New) The method of claim 20, further comprising the step of shipping educational materials to the prescriber.

24. (New) A method according to claim 20, further comprising registering in the medium the physician who prescribed said drug.

25. (New) The method of claim 20, further comprising counseling the patient as to the risks of taking the drug and advising the patient as to risk avoidance measures, in response to the risk group assignment.

26. (New) The method of claim 25, wherein the counseling comprises full disclosure of the risks.

27. (New) The method of claim 26, wherein the prescription is filled only following said full disclosure.

28. (New) The method of claim 27, wherein the fact of said full disclosure is registered in the database prior to generation of the prescription approval code.

29. (New) The method of claim 28, wherein the risk group assignment and the fact of said full disclosure is transmitted to the database by facsimile and interpreted by optical character recognition software.

30. (New) The method of claim 20, further comprising:

g. defining for each risk group a second set of information to be collected from the patient at periodic intervals;

h. obtaining the second set of information from the patient; and

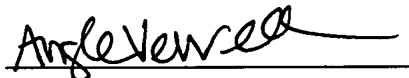
i. entering the second set of information in the database.

DOCKET NO.: CELG-0508 **PATENT**
Application No.: Not yet assigned
Preliminary Amendment - First Action Not Yet Received

REMARKS

Claims 1-19 have been canceled, and claims 20-30 have been added. Support for these claims can be found throughout the specification as originally filed. No new matter has been added. Consideration and allowance of the pending claims is respectfully requested.

Date: May 19, 2006



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Application Data Sheet

Application Information

Application number:	Not yet assigned
Filing Date:	Herewith
Application Type:	Regular - Continuation
Subject Matter:	Utility
Suggested Classification:	
Suggested Group Art Unit:	
CD-ROM or CD-R:	None
Number of CD Disks:	
Number of copies of CDs:	
Sequence Submission?	
Computer Readable Form (CRF)?	
Number of Copies of CRF:	
Title:	Methods for Delivering a Drug to a Patient While Restricting Access to the Drug by Patients for Whom the Drug May be Contraindicated
Attorney Docket Number:	CELG-0508
Request for Early Publication:	No
Request for Non-Publication:	No
Suggested Drawing Figure:	
Total Drawing Sheets:	None
Small Entity?:	No
Latin name:	
Variety denomination name:	
Petition included?:	No
Petition Type:	
Licensed US Govt. Agency:	
Contract or Grant Numbers:	
Secrecy Order in Parent Appl.?:	No

Applicant Information

Applicant Authority Type:	Inventor
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State or Province of mailing address:	New Jersey
Country of mailing address:	United States of America
Postal or Zip Code of mailing address:	08827

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Name:	
Street of Mailing Address:	
City of Mailing Address:	
State or Province of Mailing Address:	
Country of Mailing Address:	
Postal or Zip Code of Mailing Address:	
Phone number:	
Fax number:	

Representative Information

Representative Customer No.:	23377

Domestic Priority Information

This application is a continuation of U.S. Application Serial No. 11/028,144, filed January 3, 2005, which is a continuation of U.S. Application Serial No. 10/762,880, filed January 22, 2004, now U.S. Patent No. 6,869,399, which is a continuation of U.S. Application Serial No. 10/383,275, filed March 7, 2003, now U.S. Pat. No. 6,755,784, which is a continuation of U.S. Application Serial No. 09/965,155, filed September 27, 2001, now U.S. Pat. No. 6,561,977, which is a continuation of U.S. Application No. 09/694,217, filed October 23, 2000, now U.S. Pat. No. 6,315,720, the entirety of each of which is hereby incorporated by reference.

Foreign Priority Information

Country:	Application No.:	Filing Date:	Priority Claimed:

Assignee Information

Assignee name:	Celgene Corporation
Street of mailing address:	7 Powder Horn Drive
City of mailing address:	Warren
State or Province of mailing address:	New Jersey
Country of mailing address:	United States of America
Postal or Zip Code of mailing address:	07059

PATENT APPLICATION FEE DETERMINATION RECORD

Substitute for Form PTO-875 Effective December 8, 2004

Application or Docket Number: 11437551

APPLICATION AS FILED – PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA	SMALL ENTITY RATE ($)	SMALL ENTITY FEE ($)	OR	OTHER THAN SMALL ENTITY RATE ($)	OTHER THAN SMALL ENTITY FEE ($)
BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A	150.00		N/A	300.00
SEARCH FEE (37 CFR 1.16(k), (l), or (m))	N/A	N/A	N/A	$250		N/A	$500
EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A	$100		N/A	$200
TOTAL CLAIMS (37 CFR 1.16(i))	11 minus 20 = *	—	X$ 25 =		OR	X$50 =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	1 minus 3 = *	—	X100 =			X200 =	
APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $250 ($125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).						
MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))			+180=			+360=	
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL			TOTAL	1000

APPLICATION AS AMENDED – PART II

		(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	SMALL ENTITY RATE ($)	SMALL ENTITY ADDITIONAL FEE ($)	OR	OTHER THAN SMALL ENTITY RATE ($)	OTHER THAN SMALL ENTITY ADDITIONAL FEE ($)
AMENDMENT A	Total (37 CFR 1.16(i))	* 11	Minus	** 20	=	X$ 25 =		OR	X$50 =	
	Independent (37 CFR 1.16(h))	* 1	Minus	*** 3	=	X100 =		OR	X200 =	
	Application Size Fee (37 CFR 1.16(s))									
	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))					+180=		OR	+360=	
						TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	

		(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	SMALL ENTITY RATE ($)	SMALL ENTITY ADDITIONAL FEE ($)	OR	OTHER THAN SMALL ENTITY RATE ($)	OTHER THAN SMALL ENTITY ADDITIONAL FEE ($)
AMENDMENT B	Total (37 CFR 1.16(i))	*	Minus	**	=	X$ 25 =		OR	X$50 =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=	X100 =		OR	X200 =	
	Application Size Fee (37 CFR 1.16(s))									
	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))					+180=		OR	+360=	
						TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".
*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".
The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.

DOCKET NO.: CELG-0508 **PATENT**

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of:
Bruce A. Williams and Joseph K. Kaminski
Application No.: 11/437,551
Filing Date: May 19, 2006
Confirmation No.: 3533
Group Art Unit: 3736
Examiner: Not Yet Assigned
For: METHODS FOR DELIVERING A DRUG TO A PATIENT WHILE RESTRICTING ACCESS TO THE DRUG BY PATIENTS FOR WHOM THE DRUG MAY BE CONTRAINDICATED

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

ASSIGNEE POWER OF ATTORNEY

The undersigned, assignee of the entire interest in the above-identified application, hereby appoints the attorneys associated with the following customer number of the firm of WOODCOCK WASHBURN LLP, One Liberty Place - 46th Floor, Philadelphia, Pennsylvania, 19103, as attorneys for applicant(s), with full power of substitution and revocation, to prosecute this application, to make alterations and amendments therein, to receive the patent, and to transact all business in the Patent and Trademark Office connected therewith.

23377

Send all future correspondence and address all telephone calls to:

John W. Caldwell
WOODCOCK WASHBURN LLP
One Liberty Place - 46th Floor
Philadelphia PA 19103
Telephone: (215) 568-3100

2006 WW

STATEMENT UNDER 37 CFR § 3.73(b)

Celgene Corporation, a corporation of Delaware, and is also a large entity,

states that it is:

☒ the assignee of the entire right, title, and interest; or

☐ an assignee of an undivided part interest

in the patent application/patent identified above by virtue of either:

1. ☒ An assignment from the inventors of a parent application, 10/383,275 filed March 7, 2003, now U.S. Patent No. 6,755,784.

   ☒ 1. The assignment was recorded April 23, 2003 in the Patent and Trademark Office at Reel 013982, Frames 0697-0701.

OR

2. ☐ A chain of title from the inventor(s), of the patent application/patent identified above, to the current assignee as shown below:

   From: To: The document was recorded in the Patent and Trademark Office at Reel , Frame(s) , or for which a copy thereof is attached.

   From: To: The document was recorded in the Patent and Trademark Office at Reel , Frame(s) , or for which a copy thereof is attached.

   From: To: The document was recorded in the Patent and Trademark Office at Reel , Frame(s) , or for which a copy thereof is attached.

   ☐ Additional documents in the chain of title are listed on a supplemental sheet.

   ☐ Copies of assignments or other documents in the chain of title are attached.

The undersigned (whose title is supplied below) is empowered to act on behalf of the assignee, Celgene Corporation.

Signature
Name: Robert J. Hugin
Title: President and COO

Date: 7/24/06

UNITED STATES PATENT AND TRADEMARK OFFICE

CELG-0363 JWC/smv/SCT

SEPTEMBER 22, 2003

PTAS

Deputy Under Secretary of Commerce For Intellectual Property and
Deputy Director of the United States Patent and Trademark Office
Washington, DC 20231
www.uspto.gov

WOODCOCK WASHBURN LLP
STEPHEN C. TIMMINS
ONE LIBERTY PLACE - 46TH FLOOR
PHILADELPHIA, PA 19103-7301

102430442A

UNITED STATES PATENT AND TRADEMARK OFFICE
NOTICE OF RECORDATION OF ASSIGNMENT DOCUMENT

THE ENCLOSED DOCUMENT HAS BEEN RECORDED BY THE ASSIGNMENT DIVISION OF THE U.S. PATENT AND TRADEMARK OFFICE. A COMPLETE MICROFILM COPY IS AVAILABLE AT THE ASSIGNMENT SEARCH ROOM ON THE REEL AND FRAME NUMBER REFERENCED BELOW.

PLEASE REVIEW ALL INFORMATION CONTAINED ON THIS NOTICE. THE INFORMATION CONTAINED ON THIS RECORDATION NOTICE REFLECTS THE DATA PRESENT IN THE PATENT AND TRADEMARK ASSIGNMENT SYSTEM. IF YOU SHOULD FIND ANY ERRORS OR HAVE QUESTIONS CONCERNING THIS NOTICE, YOU MAY CONTACT THE EMPLOYEE WHOSE NAME APPEARS ON THIS NOTICE AT 703-308-9723. PLEASE SEND REQUEST FOR CORRECTION TO: U.S. PATENT AND TRADEMARK OFFICE, ASSIGNMENT DIVISION, BOX ASSIGNMENTS, CG-4, 1213 JEFFERSON DAVIS HWY, SUITE 320, WASHINGTON, D.C. 20231.

RECORDATION DATE: 04/23/2003

REEL/FRAME: 013982/0697
NUMBER OF PAGES: 5

BRIEF: ASSIGNMENT OF ASSIGNOR'S INTEREST (SEE DOCUMENT FOR DETAILS).

ASSIGNOR:
WILLIAMS, BRUCE A.

DOC DATE: 01/05/2001

ASSIGNOR:
KAMINSKI, JOSEPH K.

DOC DATE: 01/05/2003

ASSIGNEE:
CELGENE CORPORATION
7 POWDER HORN DRIVE
WARREN, NEW JERSEY 07059

SERIAL NUMBER: 10383275
PATENT NUMBER:

FILING DATE: 03/07/2003
ISSUE DATE:

LAZENA MARTIN, EXAMINER
ASSIGNMENT DIVISION
OFFICE OF PUBLIC RECORDS

04-22-2003

RECOR

102430442

To The Honorable Commissioner of Patents and Trac documents or copy thereof.

1. Name of conveying party(ies): 4-23-03

Bruce A. Williams
First Assignor Date of Execution

Joseph K. Kaminski
Second Assignor Date of Execution

Third Assignor Date of Execution

Fourth Assignor Date of Execution

Fifth Assignor Date of Execution

Sixth Assignor Date of Execution

Additional name(s) of conveying party(ies) attached? ☐ YES ☐ NO

2. Name and address of receiving party(ies):

Name: Celgene Corporation

Street Address: 7 Powder Horn Drive

City: Warren

State: New Jersey ZIP: 07059

Additional name(s) & address attached? ☐ YES ☒ NO

3. Nature of Conveyance (check only one):

☐ New Assignment ☐ Merger
☐ License Agreement ☐ Security Agreement
☐ Change of Name ☐ Other:

☒ Cross-reference of Assignment filed in United States Application No. 09/694,217, recorded on 1/18/01 at Reel No. 011469 and Frame No. 0882.

OFFICE OF PUBLIC RECORDS
2003 APR 23 AM 7:50
FINANCE SECTION

4. Identification of Application number(s), patent number(s) OR date of execution of application to which assignment refers:

Application Nos.:	Patent Nos.:	Date application was signed by the first named executing inventor
10/383,275 filed March 7, 2003		(Fill-in this date only if assignment is filed together with a new application)

5. Name and address of party to whom correspondence concerning documents should be mailed:

Name: Stephen C. Timmins, Esq.
WOODCOCK WASHBURN LLP
One Liberty Place - 46th Floor
Philadelphia, Pennsylvania 19103-7301
215-568-3100

6. Total number of applications and patents involved: 1

7. Total fee (37 CFR 3.41): $40.00
☒ Enclosed
☐ Authorized to be charged to Deposit Account Number 23-3050

8. **Please charge any deficiency or credit any overpayment to Deposit Account Number 23-3050**

DO NOT USE THIS SPACE

9. Statement and signature.

To the best of my knowledge and belief, the foregoing information is true and correct and any attached copy is a true copy of the original document.

Stephen C. Timmins/48,481
Name of Person Signing/Reg. No.

Signature

4/18/03
Date

Total number of pages including cover sheet, assignment document and additional pages attached thereto: 5

Mail documents to be recorded with required cover sheet information to:

Commissioner of Patents and Trademarks
Box Assignments
Washington, D.C. 20231

04/24/2003 LMUELLER 00000170 10383275
FC:8021 40.00 OP

PATENT
Joint Inventors

(Pending Application; Serial No. Known)

DOCKET NO.: CELG-0188

ASSIGNMENT

WHEREAS, we **Bruce A. Williams and Joseph K. Kaminski**, hereinafter referred to as the assignors, residing respectively at **37 Winding Way, Flemington, New Jersey 08822 and 20 Kalan Farm Road, Hampton, New Jersey 08827** are the joint inventors of certain inventions or improvements for which we have made application for Letters Patent to the United States, identified as Serial No. **09/694,217**, filed **October 23, 2000**, entitled **METHODS FOR DELIVERING A DRUG TO A PATIENT WHILE AVOIDING THE OCCURRENCE OF AN ADVERSE SIDE EFFECT KNOWN OR SUSPECTED OF BEING CAUSED BY THE DRUG**; and

WHEREAS, **Celgene Corporation** hereinafter referred to as the assignee, of **7 Powder Horn Drive, Warren, New Jersey 07059**, a corporation of **Delaware**, is desirous of acquiring the entire right, title and interest in and to the said inventions or improvements and in and to the said application, and in, to and under any and all Letters Patent which may be granted on or as a result thereof in any and all countries:

NOW, THEREFORE, for and in consideration of the sum of One Dollar ($1.00) to each of us in hand paid by said assignee, and other good and valuable consideration, the receipt of which is hereby acknowledged, we, the said assignors, have sold, assigned, transferred and set over, and by these presents do hereby sell, assign, transfer and set over to said assignee, the entire right, title and interest in and to said inventions or improvements and said application and any and all continuations, divisions and renewals of and substitutes for said application, and in, to and under any and all Letters Patent which may be granted on or as a result thereof in the United States and any and all other countries, and any reissue or reissues or extension or extensions of said Letters Patent, and assign to and authorize said assignee, to file in our names applications for Letters Patent in all countries, the same to be held and enjoyed by said assignee, its successors, assigns, nominees or legal representatives, to the full end of the term or terms for which said Letters Patent respectively may be granted, reissued or extended, as fully and entirely as the same would have been held and enjoyed by us had this assignment, sale and transfer not been made.

AND we hereby covenant that we have full right to convey the entire interest herein assigned, and that we have not executed and will not execute any agreement in conflict herewith, and we further covenant and agree that we will each time request is made and without undue delay, execute and deliver all such papers as may be necessary or desirable to perfect the title to said inventions or improvements, said application and said Letters Patent to said assignee, its successors, assigns, nominees, or legal representatives, and each of us agrees to communicate to said assignee or to its nominee all known facts respecting said inventions or improvements, said application and said Letters Patent, to testify in any legal proceedings, to

sign all lawful papers to execute all disclaimers and divisional, continuing, reissue and foreign applications, to make all rightful oaths, and generally to do everything possible to aid said assignee, its successors, assigns, nominees and legal representatives to obtain and enforce for its or their own benefit proper patent protection for said inventions or improvements in any and all countries.

AND we hereby authorize and request the Commissioner of Patents and Trademarks of the United States and any official of any country or countries foreign to the United States whose duty it is to issue patents on applications as aforesaid, to issue to said assignee, as assignee of the entire right, title and interest, any and all Letters Patent for said inventions or improvements, including any and all Letters Patent of the United States which may be issued and granted on or as a result of the application aforesaid, in accordance with the terms of this assignment.

IN WITNESS WHEREOF, we have hereunto set our hands and seals.

_____ (L.S.)
Bruce A. Williams

_____ (L.S.)
Joseph K. Kaminski

[WHERE ALL INVENTORS SIGN BEFORE THE SAME NOTARY:]

_____:
: SS
COUNTY OF Somerset :

On this 5th day of Jan, year of 01, before me personally came the above named Bruce William + Joseph Karwicki to me personally known and known to me to be the same individual who executed the foregoing assignment, and who acknowledged to me that execution of the same was of that person's own free will for the use and purposes therein set forth.

Jacqueline M Keller
Notary Public

JACQUELINE M. KELLER
NOTARY PUBLIC OF NEW JERSEY
My Commission Expires May 22, 2002

[WHERE INVENTORS SIGN BEFORE SEPARATE NOTARIES:]

_____:
: SS
COUNTY OF _____:

On this _____ day of _____, year of_____, before me personally came the above named _____ to me personally known and known to me to be the same individual who executed the foregoing assignment, and who acknowledged to me that execution of the same was of that person's own free will for the use and purposes therein set forth.

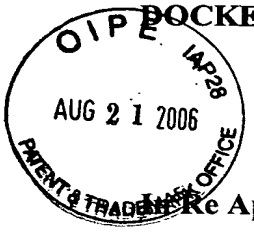
_____
Notary Public

_____:
: SS
COUNTY OF _____:

On this _____ day of _____, year of_____, before me personally came the above named _____ to me personally known and known to me to be the same individual who executed the foregoing assignment, and who acknowledged to me that execution of the same was of that person's own free will for the use and purposes therein set forth.

_____
Notary Public

IFW



DOCKET NO.: CELG-0508 **PATENT**

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of:

Bruce A. Williams, et al. **Confirmation No.: 3533**

Application No.: 11/437,551 **Group Art Unit: 3736**

Filing Date: May 19, 2006 **Examiner: Not yet assigned**

For: Methods For Delivering A Drug To A Patient While Restricting Access To The Drug By Patients For Whom The Drug May Be Contraindicated

DATE OF DEPOSIT: August 18, 2006

I HEREBY CERTIFY THAT THIS PAPER IS BEING DEPOSITED WITH THE UNITED STATES POSTAL SERVICE AS FIRST CLASS MAIL, POSTAGE PREPAID, ON THE DATE INDICATED ABOVE AND IS ADDRESSED TO THE UNITED STATES PATENT AND TRADEMARK OFFICE, P.O. BOX 1450, ALEXANDRIA, VA 22313-1450.

Heather Kite

TYPED NAME: Heather Kite

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

INFORMATION DISCLOSURE STATEMENT

Pursuant to 37 CFR § 1.56 and in accordance with 37 CFR §§ 1.97-1.98, information relating to the above-identified application is hereby disclosed. Inclusion of information in this statement is not to be construed as an admission that this information is material as that term is defined in 37 CFR § 1.56(b).

☒ In accordance with § 1.97(b), since this Information Disclosure Statement is being filed either within three months of the filing date of the above-identified application, within three months of the date of entry into the national stage of the above identified application as set forth in § 1.491, before the mailing date

of a first Office Action on the merits of the above-identified application, or before the mailing date of a first Office Action after the filing of request for continued examination under § 1.114, no additional fee is required.

☐ In accordance with § 1.97(c), this Information Disclosure Statement is being filed after the period set forth in § 1.97(b) above but before the mailing date of either a Final Action under § 1.116 or a Notice of Allowance under § 1.311, or before an action that otherwise closes prosecution in the application, therefore:

- ☐ Certification in Accordance with § 1.97(e) is attached; or
- ☐ The fee of **$180.00** as set forth in § 1.17(p) is attached.

☐ In accordance with § 1.97(d), this Information Disclosure Statement is being filed after the mailing date of either a Final Action under § 1.113 or a Notice of Allowance under § 1.311 but before, or simultaneously with, the payment of the Issue Fee, therefore included are: Certification in Accordance with § 1.97(e); and the submission fee of **$180.00** as set forth in § 1.17(p).

☐ Copies of reference numbers listed on the attached Form PTO-1449 are enclosed herewith.

☐ Copies of reference numbers - on the attached Form PTO 1449 are not required to be submitted pursuant to 37 CFR § 1.98(a)(2)(i).

☒ Copies of references 1-56 are not being submitted because they were previously cited by or submitted to the U.S. Patent and Trademark Office in patent application number 11/028,144, filed January 3, 2005, for which a claim for priority under 35 U.S.C. § 120 has been made in the instant application.

Please charge any deficiency or credit any overpayment to Deposit Account No. 23-3050. This form is submitted in duplicate.

Date: August 18, 2006

Angela Verrecchio
Registration No. 54,510

WOODCOCK WASHBURN LLP
One Liberty Place - 46th Floor
Philadelphia, PA 19103
Telephone: (215) 568-3100
Facsimile: (215) 568-3439

Form PTO-1449 Modified	Docket No. CELG-0508	Application No. 11/437,551
List of Patent and Publications Cited by Applicant (Use several sheets if necessary) U.S. Department of Commerce Patent and Trademark Office	Applicant Bruce A. Williams, et al.	
	Filing Date May 19, 2006	Group 3736
	Confirmation No. 3533	

U. S. PATENT DOCUMENTS

Examiner Initial		Document No.	Date	Name	Class	Subclass
	1	5,299,121	03/20/94	Brill, et al.	600	301
	2	5,594,637	01/14/97	Eisenberg, et al.	600	300
	3	5,619,991	04/15/97	Sloane	600	300
	4	5,660,176	08/26/97	Iliff	600	300
	5	5,832,449	11/03/98	Cunningham	705	3
	6	5,845,255	12/01/98	Mayaud	705	3
	7	5,974,203	10/26/99	Tadokoro, et al.	382	309
	8	6,014,631	01/11/00	Teagarden, et al.	705	3
	9	6,045,501	04/04/00	Elsayed, et al.	600	300
	10	6,055,507	04/25/00	Cunningham	705	3
	11	6,063,026	05/16/00	Schauss, et al.	600	300
	12	6,128,620	10/03/00	Pissanos, et al.	707	102
	13	6,131,090	10/10/00	Basso, Jr., et al.	706	23
	14	6,202,923 B1	03/20/01	Boyer, et al.	235	375
	15	6,315,720 B1	11/13/01	Williams, et al.	600	300
	16	6,561,976 B2	05/13/03	Elsayed, et al.	600	300
	17	6,561,977 B2	05/13/03	Williams, et al.	600	300
	18	6,561,978 B2	05/13/03	Elsayed, et al.	128	920
	19	6,755,784	06/29/04	Williams, et al.	600	300
	20	6,755,784	06/2004	Williams et al.	600	300

EXAMINER	DATE CONSIDERED

Form PTO-1449 Modified List of Patent and Publications Cited by Applicant (Use several sheets if necessary) U.S. Department of Commerce Patent and Trademark Office	Docket No. CELG-0508	Application No. 11/437,551
	Applicant Bruce A. Williams, et al.	
	Filing Date May 19, 2006	Group 3736
	Confirmation No. 3533	

U. S. PATENT DOCUMENTS

Examiner Initial		Document No.	Date	Name	Class	Subclass
	21	6,767,326 B2	07/27/04	Elsayed, et al.	600	300
	22	6,869,399	03/2005	Williams et al.	600	300
	23	6,908,432 B2	06/21/05	Elsayed,e t al.	600	300
	24	2005/0090425 A1	04/28/05	Reardan, et al.		
	25	2005/0216309 A1	09/29/05	Reardan, et al.		
	26	2005/0222874 A1	10/06/05	Reardan, et al.		

EXAMINER	**DATE CONSIDERED**

Form PTO-1449 Modified List of Patent and Publications Cited by Applicant (Use several sheets if necessary) U.S. Department of Commerce Patent and Trademark Office	Docket No. CELG-0508	Application No. 11/437,551
	Applicant Bruce A. Williams, et al.	
	Filing Date May 19, 2006	Group 3736
	Confirmation No. 3533	

FOREIGN PATENT DOCUMENTS

Examiner Initial		Document No.	Date	Country	Translation YES	Translation NO
	27	00/51053	08/31/00	WO		
	28	98/13783	04/02/98	WO		
	29	98/58338	12/23/98	WO		
	30	99/10829	03/04/99	WO		
	31	02/35440 A1	05/02/02	WO		
	32	2 352 619 A1	01/06/03	CA		

EXAMINER	DATE CONSIDERED

Form PTO-1449 Modified List of Patent and Publications Cited by Applicant (Use several sheets if necessary) U.S. Department of Commerce Patent and Trademark Office	Docket No. CELG-0508	Application No. 11/437,551
	Applicant Bruce A. Williams, et al.	
	Filing Date May 19, 2006	Group 3736
	Confirmation No. 3533	

NON-PATENT DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

	33	Bakken, K., et al., "Local monitoring center for clozapine therapy: quality assurance of drug treatment in a group of psychiatric patients," *Tidsskr Nor Laegeforen nr.*, **1998**, *118*, 1076 – 1078 (English abstract middle of page 1076)
	34	Bastani, B., et al., "Development of the clozaril patient management system," *Psychopharmacology*, **1989**, *99*, S122 – S125
	35	Behm, G.A., Jr., No Title, *Am. Pharmacy 13th APhA Annual Meeting Highlights*, **1990**, *NS30(6)*, page 7
	36	Bender, K.J., "FDA approves reduced clozapine monitoring; increased patient access versus increased risk," *Psychiatric Times*, **1998**, *Vol. XV, Issue 5*
	37	Black, L.L., et al., "A centralized system for monitoring clozapine use in British Columbia," *Psychiatric Services*, **1996**, *47(1)*, 81-83
	38	Bruera, E., and Neumann, C. M., "The uses of psychotropics in symptom management in advanced cancer," *Psycho-Oncology.*, **1998,** 7, 346-358
	39	Clark, T. E.., et al., "Thalidomide Capsules, A review of the first 18 months of spontaneous postmarketing adverse event surveillance, including off-label presrcribing," *Drug Safety.*, **2001**, 24(2), 87-117
	40	Dimopoulis, M. A., and Eleutherakis-Papaiakovou, V., "Adverse effects of Thalidomide administration in patients with neoplastic diseases," *Am. J. Med.*, **October 1, 2004**, 117, 508-515
	41	Freeman, D.J., et al., "Will routine therapeutic drug monitoring have a place in clozapine therapy?," *Clinical Pharmacokinetics*, **1997**, *32(2)*, 93-100
	42	Honigfeld, G., et al., "Reducing clozapine-related morbidity and mortality: 5 years of experience with the clozaril national registry," *J. Clin. Psychiatry*, **1998**, *59(Suppl. 3)*, 3-7
	43	Kumar, V., "Clozaril monitoring systems, registry data and analyses," Presentation, *Novartis*, **2002**, 44 pages
	44	Lieberman, J.A., et al., "A report of clozapine – induced agranulocytosis in the United States (Incidence and risk factors)," *Drug Safety, Proceedings of a symposium held in London*, **1991**, Hoffbrand, A.V, et al. (Eds.), 1-2
	45	Love, D.J., et al., "Computerized relational database for monitoring clozapine therapy," *Am. J. Hosp. Pharm.*, **1993**, 1657-1662
	46	Martin, S., "APhA says plan continues to interfere with pharmacists' practice prerogatives," *Am. Pharmacy*, **1991**, *NS31(5)*, 30-31

EXAMINER	**DATE CONSIDERED**

Form PTO-1449 Modified List of Patent and Publications Cited by Applicant (Use several sheets if necessary) U.S. Department of Commerce Patent and Trademark Office	Docket No. CELG-0508	Application No. 11/437,551
	Applicant Bruce A. Williams, et al.	
	Filing Date May 19, 2006	Group 3736
	Confirmation No. 3533	

NON-PATENT DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)		
	47	Mordue, H.W., "Rational approach to clozaril distribution," *Am. Pharmacy*, **1990**, *NS30(6)*, page 7
	48	Oyesanmi, O., et al., "Hematologic side effects of psychotropics," *Psychosomatics*, **1999**, *40*, 414-421
	49	Patt, Y.Z, et al., "Durable Clinical response of refractory hepatocellular to orally administered thalidomide," *Am. J. Clin. Oncol. (CCT.*, **2000**, 23(3), 319-321
	50	Peck, C.C., et al., "FDA's position on the clozaril patient management system," *Hospital & Community Psychiatry*, **1990**, *41(8)*, 876-877
	51	Richardson, P, et al., "Thalidomide: Emerging role in cancer medicine," *Annu. Rev. Med.*, **2002**, 53, 629-657
	52	Richardson, P., et al., "Thalidomide: The revival of a drug with Therapeutic promise in the treatment of cancer", In: Cancer: Principles and Practice of Oncology, 6th Ed., DeVita VT, Hellman S, Rosenberg SA, editors. Lippincott, Williams, and Wilkins, Philadelphia PA, **2001**, 1-18.
	53	Singhal, S. and Mehta, J., "Peer Viewpoint," *J. Supportive Oncology*, 1(3), **September/October 2003**, 200-201
	54	Somers, G. F., "Pharmacological Properties of Thalidomide (α-Phalidimido Glutarimide) a New Sedative-Hypnotic Drug," *Brit. J. Pharmacol.*, **1960**, 15, 111-116
	55	Teo, S. K., et al., "Clinical pharmacokinetics of thalidomide," *Clin Pharmacokinetics*, **April 2004**, 43(5), 311-327
	56	Thomas, M. and Doss, D, "Thalidomide Nursing Roundtable Update," *American Academy of CME, Inc. and OmegaMed Inc., publishers.*, **September 2002**

EXAMINER	**DATE CONSIDERED**

DOCKET NO.: CELG-0508 **PATENT**

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of:

Bruce A. Williams, et al. **Confirmation No.: 3533**

Application No.: 11/437,551 **Group Art Unit: 3736**

Filing Date: May 19, 2006 **Examiner: Michael C. Astorino**

FOR: Methods For Delivering A Drug To A Patient While Restricting Access To The Drug By Patients For Whom The Drug May Be Contraindicated

DATE OF DEPOSIT: May 18, 2007

I HEREBY CERTIFY THAT THIS PAPER IS BEING DEPOSITED WITH THE UNITED STATES POSTAL SERVICE AS FIRST CLASS MAIL, POSTAGE PREPAID, ON THE DATE INDICATED ABOVE AND IS ADDRESSED TO THE UNITED STATES PATENT AND TRADEMARK OFFICE, P.O. BOX 1450, ALEXANDRIA, VA 22313-1450.

TYPED NAME: Angela Verrecchio
REGISTRATION NO.: 54,510

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Pursuant to 37 CFR § 1.56 and in accordance with 37 CFR §§ 1.97-1.98, information relating to the above-identified application is hereby disclosed. Inclusion of information in this statement is not to be construed as an admission that this information is material as that term is defined in 37 CFR § 1.56(b).

☒ In accordance with § 1.97(b), since this Information Disclosure Statement is being filed either within three months of the filing date of the above-identified application, within three months of the date of entry into the national stage of

the above identified application as set forth in § 1.491, before the mailing date of a first Office Action on the merits of the above-identified application, or before the mailing date of a first Office Action after the filing of request for continued examination under § 1.114, no additional fee is required.

☒ Copies of reference numbers 58-86 listed on the attached Form PTO-1449 are enclosed herewith.

☒ A Copy of reference number 57 on the attached Form PTO 1449 is not required to be submitted pursuant to 37 CFR § 1.98(a)(2)(i).

There are no listed references which are not in the English language.

Please charge any deficiency or credit any overpayment to Deposit Account No. 23-3050. This form is submitted in duplicate.

Date: May 18, 2007

Angela Verrecchio
Registration No. 54,510

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Form PTO-1449 Modified List of Patent and Publications Cited by Applicant (Use several sheets if necessary) U.S. Department of Commerce Patent and Trademark Office	Docket No. CELG-0508	Application No. 11/437,551
	Applicant Bruce A. Williams, et al.	
	Filing Date May 19, 2006	Group 3736
	Confirmation No. 3533	

U. S. PATENT DOCUMENTS

Examiner Initial		Document No.	Date	Name	Class	Subclass
	57	5,758,095	05/26/98	Albaum et al.	395	202

FOREIGN PATENT DOCUMENTS

Examiner Initial		Document No.	Date	Country	Translation YES	Translation NO

EXAMINER	DATE CONSIDERED

Form PTO-1449 Modified List of Patent and Publications Cited by Applicant (Use several sheets if necessary) U.S. Department of Commerce Patent and Trademark Office	Docket No. CELG-0508	Application No. 11/437,551
	Applicant Bruce A. Williams, et al.	
	Filing Date May 19, 2006	Group 3736
	Confirmation No. 3533	

NON-PATENT DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)		
	58	*Medical Marketing & Media*, "Managing a product under attack: a firsthand report on Clozaril: Interview with Sandoz Ltd.'s director of product marketing, Barbara Rosengren and assistant director Gilbert Honigfeld," September 20, 1991,Vol. 26, No. 10, page 6
	59	Pastuszak, A. et al., "Use Of The Retinoid Pregnancy Prevention Program In Canada: Patterns Of Contraception Use In Women Treated With Isotretinoin And Etretinate," *Reproductive Toxicology*, 1994, 8(1), 63-68
	60	Sittig, D. F. et al., "Computer-based Physician Order Entry: The state of the Art," *J. Amer. Med. Inform. Assoc.*, Mar/Apr 1994, 1(2), 108-123
	61	Mitchell, A. A. et al., "A Pregnancy-Prevention Program in Women of Childbearing Age Receiving Isotretinoin," *N. Engl. J. Med.*, July 13, 1995, 333(2), 101-106
	62	Trussell, J., "Contraceptive Efficacy," *Arch. Dermatol.*, Sep 1995, 131, 1064-1068
	63	Honigfeld, G., "Effects Of The Clozapine National Registry System on Incidence of Deaths Related to Agranulocytosis," *Psychiatric Services*, January 1996, 47(1), 52-56
	64	"Thalidomide protocols and patient materials designed by FDA for studies without commercial sponsors," "*The Pink Sheet*", November 18, 1996, 58(047), page T&G-4
	65	Physician's Desk Reference, 1997, pp. 2252-2254, 2377-2380
	66	*FDA's Forty-Seventh Meeting of the Dermatologic and Ophthalmic Drugs Advisory Committee*, September 4-5, 1997
	67	Thalidomide: Potential Benefits and Risks. An Open Public Scientific Workshop, Program and Abstracts, September 9-10, 1997
	68	Thalidomide: Potential Benefits and Risks. An Open Public Scientific Workshop, Transcript: NIH Testimony from September 9, 1997: http://www.fda.gov/oashi/patrep/nih99.html

EXAMINER	**DATE CONSIDERED**

Form PTO-1449 Modified List of Patent and Publications Cited by Applicant (Use several sheets if necessary) U.S. Department of Commerce Patent and Trademark Office	Docket No. CELG-0508	Application No. 11/437,551
	Applicant Bruce A. Williams, et al.	
	Filing Date May 19, 2006	Group 3736
	Confirmation No. 3533	

NON-PATENT DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)		
	69	Thalidomide: Potential Benefits and Risks. An Open Public Scientific Workshop, Transcript: NIH Testimony from September 10, 1997: http://www.fda.gov/oashi/patrep/nih910.html
	70	Janet Woodcock, Director, Center for Drug Evaluation and Research, "Supervisory Review of NDA 20-785," July 7, 1998
	71	"Hoechst Arava Pregnancy Registry Recommended To Track Teratogenicity," *"The Pink Sheet"*, August 17, 1998, Vol. 60, Number 033, page 23
	72	Reference Guide "THALIDOMID™ (thalidomide): Clinical Information and Prescribing Guidelines," Celgene Corporation, 9/98
	73	Bates, D. W. et al., "Effect of Computerized Physician Order Entry and a Team Intervention on Prevention of Serious Medication Errors," *JAMA*, October 21, 1998, 280(15), 1311-1316
	74	System for Thalidomide Education and Prescribing Safety, "THALIDOMID™ (thalidomide): Balancing the Benefits and the Risks," Celgene Corporation, 11/98
	75	Zeldis, J. B. et al., "S.T.E.P.S.™: A Comprehensive Program for Controlling and Monitoring Access to Thalidomide," *Frontiers in Fetal Health: A Global Perspective*, The Fetal Centre at The Hospital for Sick Children, Toronto, Canada, Vol. 1, Number 2, August 1999
	76	Roche's Press Release Regarding Pregnancy Prevention Program for Women for Women on Accutane, October 31, 2001
	77	Villahermosa, L. G. et al., "A Randomized, Double-Blind, Double-Dummy, Controlled Dose Comparison of Thalidomide for Treatment of Erythema Nodosum Leprosum," *Am. J. Trop. Med. Hyg.*, 2005, 72(5), 518-526
	78	Uhl, K. et al., "Thalidomide Use in the US: Experience with Pregnancy Testing in the S.T.E.P.S.® Programme," *Drug Safety*, 2006, 29(4), 321-329
	79	"About the CNR," Website Printout: https://www.clozarilcare.com/care/NewUsrReqPersonal.jsp
	80	Complaint filed 1/18/2007 in NJ: *Celgene Corp. v. Barr Laboratories*, Case No. 2:07-cv-00286-PGS-RJH

EXAMINER	**DATE CONSIDERED**

Form PTO-1449 Modified List of Patent and Publications Cited by Applicant (Use several sheets if necessary) U.S. Department of Commerce Patent and Trademark Office	Docket No. CELG-0508	Application No. 11/437,551
	Applicant Bruce A. Williams, et al.	
	Filing Date May 19, 2006	Group 3736
	Confirmation No. 3533	

NON-PATENT DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)		
	81	Defendant Barr Laboratories, Inc.'s Answer, Counterclaims and Demand for Jury Trial filed 3/01/2007 in NJ: *Celgene Corp. v. Barr Laboratories*, Case No. 2:07-cv-00286-PGS-RJH
	82	Fax sent 10/14/04 from Ian Hilley of GenPharm, Inc. to John Jackson of Celgene Corp. re: Isotretinoin Pregnancy Risk Management Program
	83	Press Release dated 11/23/04, "Isotretinoin Makers Reach Agreement with Celgene on S.T.E.P.S. Risk Management Patents,"
	84	Notification letter dated 12/5/06 from Sterne Kessler to Celgene Corporation re: Notification Pursuant to § 505(j)(2)(B)(ii) of the Federal Food, Drug and Cosmetic Act
	85	Notification letter dated 12/15/06 from Sterne Kessler to Celgene Corporation re: Supplemental Notification Pursuant to § 505(j)(2)(B)(ii) of the Federal Food, Drug and Cosmetic Act
	86	Notification letter dated 12/19/06 from Sterne Kessler to Celgene Corporation re: Supplemental Notification Pursuant to § 505(j)(2)(B)(ii) of the Federal Food, Drug and Cosmetic Act

EXAMINER	**DATE CONSIDERED**

DOCKET NO.: CELG-0508 **PATENT**
Application No.: 11/437,551
2nd Preliminary Amendment - First Action Not Yet Received

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:
Bruce A. Williams and Joseph K. Kaminski

Confirmation No.: **3533**

Application No.: **11/437,551**

Group Art Unit: **3626**

Filing Date: **May 19, 2006**

Examiner: **Lena Najarian**

For: **Methods for Delivering a Drug To A Patient While Restricting Access To The Drug By Patients For Whom the Drug May Be Contraindicated**

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

PRELIMINARY AMENDMENT PURSUANT TO 37 CFR § 1.115

Preliminary to examination of the above-captioned patent application, please amend the application as follows:

☐ **Amendments to the Specification** begin on page of this paper.

☒ **Amendments to the Claims** are reflected in the listing of the claims which begins on page 2 of this paper.

☐ **Amendments to the Drawings** begin on page of this paper and include an attached replacement sheet.

☒ **Remarks** begin on page 10 of this paper.

This listing of claims will replace all prior versions, and listings, of claims in the application.

Listing of Claims:

Claims 1-30 (Canceled).

31. (New) A method of treating a patient, suffering from erythema nodosum leprosum, with thalidomide, said method comprising permitting prescriptions for thalidomide to be filled by a pharmacy only after the pharmacy has retrieved an approval code for the prescription from a computer readable medium.

32. (New) A method of treating a male patient, suffering from erythema nodosum leprosum, with thalidomide, said method comprising permitting prescriptions for thalidomide to be filled by a pharmacy only after the pharmacy has retrieved an approval code for the prescription, wherein the generation of the prescription approval code comprises the following steps:

(a) registering a prescriber and the pharmacy with a distributor of thalidomide;

(b) determining whether the patient is able to understand and reliably carry out instructions;

(c) upon determination that the patient is able to carry out the instructions, providing oral and written warnings of the hazard of taking thalidomide and exposing fetus to the drug;

(d) further providing oral and written warnings of the risk of possible contraception failure and of the need to use barrier contraception when having sexual intercourse with women of child bearing potential;

(e) obtaining acknowledgement of said warnings from the patient;

(f) registering the patient with the distributor; and

(g) upon obtaining the acknowledgement and registration, generating the prescription approval code to be retrieved by the pharmacy before the prescription is filled.

33. (New) The method of claim 32, wherein the acknowledgement requires the patient's acknowledgement of one or more of the following:

(a) the understanding that thalidomide must not be taken if unprotected sex cannot be avoided;

(b) the understanding of potential birth defects;

(c) that the patient has been advised of the need for barrier contraception by the prescriber;

(d) the obligation to inform the prescriber if the patient's sexual partner is suspected of becoming or being pregnant;

(e) that thalidomide is solely for the use of the patient himself and must not be shared with any other person;

(f) that the patient has read the information brochure or viewed the information film on thalidomide;

(g) that the semen or blood must not be donated during the thalidomide treatment;

(h) that all of the patient's inquiries regarding thalidomide treatment have been answered by the prescribing physician; or

(i) the patient's understanding that participation in a survey and patient registry is required during the thalidomide treatment.

34. (New) The method of claim 32 further comprising providing the patient, prior to generation of the approval code, with warnings of the side effects associated with administration of thalidomide, wherein said side effects are non-teratogenic side effects.

35. (New) The method of claim 32 further comprising obtaining a written authorization by the prescriber prior to generation of the approval code.

36. (New) The method of claim 32, wherein the prescription approval code is retrieved from a computer readable storage medium.

37. (New) The method of claim 32, wherein the acknowledgement is a written informed consent.

38. (New) The method of claim 37, wherein the written informed consent is registered in the medium prior to generation of the prescription approval code.

39. (New) A method of treating a female patient, suffering from erythema nodosum leprosum, with thalidomide, said method comprising permitting prescriptions fro thalidomide to be filled by a pharmacy only after the pharmacy has retrieved an approval code for the prescription, wherein the generation of the prescription approval code comprises the following steps:

(a) registering a prescriber and the pharmacy with a distributor of thalidomide;

(b) determining whether the patient is able to understand and reliably carry out instructions;

(c) upon determination that the patient is able to carry out the instructions, determining whether the patient is of child bearing potential;

(d) upon determining that the patient is of child bearing potential, providing oral and written warnings of the hazard of taking thalidomide and exposing fetus to the drug;

(e) further providing oral and written warnings of the risk of possible contraception failure and of the need to simultaneous use of two reliable forms of contraception;

(f) obtaining acknowledge of said warnings from the patient;

(g) determining, prior to the scheduled beginning of the thalidomide therapy, whether the patient is pregnant;

(h) registering the patient with the distributor; and

(i) generating the prescription approval code to be retrieved by the pharmacy before the prescription is filled.

40. (New) The method of claim 39, wherein the acknowledgement requires the patient's acknowledgement of one or more of the following:

(a) the understanding that thalidomide must not be taken if the patient is pregnant, breastfeeding a baby, or able to get pregnant and not using birth controls;

(b) the understanding of potential birth defects;

(c) the warning received by the prescriber regarding said birth defects;

(d) the understanding of the need for at least two forms of contraception prior to, during, and subsequent to thalidomide treatment;

(e) the obligation to undergo a pregnancy test prior to starting thalidomide treatment;

(f) the obligation to undergo a pregnancy test during the thalidomide treatment;

(g) the obligation to discontinue thalidomide treatment and inform theprescriber in the case that the patient is suspected of becoming or being pregnant;

(h) that the patient is not currently pregnant and will not try to become pregnant for at least 4 weeks after the completion of thalidomide treatment;

(i) that thalidomide is solely for the use of the patient herself and must not be shared with any other person;

(j) that the patient has read the information brochure or viewed the information film on thalidomide;

(k) that the blood must not be donated during the thalidomide treatment;

(l) that all of the patient's inquiries regarding thalidomide treatment have been answered by the prescriber; or

(m) the patient's understanding that participation in a survey and patient registry is required during the thalidomide treatment.

41. (New) The method of claim 39 further comprising providing the patient, prior to generation of the approval code, with warnings of the side effects associated with administration of thalidomide, wherein said side effects are non-teratogenic side effects.

42. (New) The method of claim 39 further comprising obtaining a written authorization by the prescriber prior to generation of the approval code.

43. (New) The method of claim 39, wherein the prescription approval code is retrieved from a computer readable storage medium.

44. (New) The method of claim 39, wherein the acknowledgement is a written informed consent.

45. (New) The method of claim 44, wherein the informed written consent is registered in the medium prior to generation of the prescription approval code.

46. (New) A method of treating a male patient, suffering from erythema nodosum leprosum, with thalidomide, said method comprising permitting prescriptions for thalidomide to be filled by a pharmacy only after the pharmacy has retrieved an approval code for the prescription from a computer readable storage medium, wherein the generation of the prescription approval code comprises the following steps:

(A) registering a prescriber and the pharmacy in the computer readable storage medium;

(B) determining whether the patient is able to understand and reliably carry out instructions;

(C) upon determination that the patient is able to carry out instructions, providing oral and written warnings of the hazard of taking thalidomide and exposing fetus to the drug;

(D) further providing oral and written warnings of the risk of possible contraception failure and of the need to use barrier contraception when having sexual intercourse with women of child bearing potential;

(E) obtaining informed consent from the patient;

(F) registering the patient in the computer readable storage medium; and

(G) upon obtaining the informed consent and registration, generating the prescription approval code to be retrieved by the pharmacy before the prescription is filled, wherein said informed consent requires the patient's acknowledgement of one or more of the following:

(a) the understanding that thalidomide must not be taken if unprotected sex cannot be avoided;

(b) the understanding of potential birth defects;

(c) that the patient has been advised of the need for barrier contraception by the prescriber;

(d) the obligation to inform the prescriber if the patient's sexual partner is suspected of becoming or being pregnant;

(e) that thalidomide is solely for the use of the patient himself and must not be shared with any other person;

(f) that the patient has read the information brochure or viewed the information film on thalidomide;

(g) that the semen or blood must not be donated during the thalidomide treatment;

(h) that all of the patient's inquiries regarding thalidomide treatment have been answered by the prescribing physician; or

(i) the patient's understanding that participation in a survey and patient registry is required during the thalidomide treatment.

47. (New) The method of claim 46 further comprising providing the patient, prior to generation of the approval code, with warnings of the side effects associated with administration of thalidomide, wherein said side effects are non-teratogenic side effects.

48. (New) The method of claim 46 further comprising obtaining a written authorization by the prescriber prior to generation of the approval code.

49. (New) A method of treating a female patient, suffering from erythema nodosum leprosum, with thalidomide, said method comprising permitting prescriptions for thalidomide to be filled by a pharmacy only after the pharmacy has retrieved an approval code for the prescription from a computer readable storage medium, wherein the generation of the prescription approval code comprises the following steps:

(A) registering a prescriber and the pharmacy in the computer readable storage medium;

(B) determining whether the patient is able to understand and reliably carry out instructions;

(C) upon determination that the patient is able to carry out instructions, determining whether the patient is of child bearing potential;

(D) upon determining that the patient is of child bearing potential, providing oral and written warnings of the hazard of taking thalidomide and exposing fetus to the drug;

(E) further providing oral and written warnings of the risk of possible contraception failure and of the need to simultaneous use of two reliable forms of contraception;

(F) obtaining informed consent from the patient;

(G) determining, prior to the scheduled beginning of the thalidomide therapy, whether the patient is pregnant;

(H) registering the patient in the computer readable storage medium; and

(I) generating the prescription approval code to be retrieved by the pharmacy before the prescription is filled,

wherein said informed consent requires the patient's acknowledgement of one or more of the following:

(a) the understanding that thalidomide must not be taken if the patient is pregnant, breastfeeding a baby, or able to get pregnant and not using birth controls;

(b) the understanding of potential birth defects;

(c) the warning received by the prescriber regarding said birth defects;

(d) the understanding of the need for at least two forms of contraception prior to, during, and subsequent to thalidomide treatment;

(e) the obligation to undergo a pregnancy test prior to starting thalidomide treatment;

(f) the obligation to undergo a pregnancy test during the thalidomide treatment;

(g) the obligation to discontinue thalidomide treatment and inform the prescriber in the case that the patient is suspected of becoming or being pregnant;

(h) that the patient is not currently pregnant and will not try to become pregnant for at least 4 weeks after the completion of thalidomide treatment;

(i) that thalidomide is solely for the use of the patient herself and must not be shared with any other person;

(j) that the patient has read the information brochure or viewed the information film on thalidomide;

(k) that the blood must not be donated during the thalidomide treatment,

(l) that all of the patient's inquiries regarding thalidomide treatment have been answered by the prescriber; or

(m) the patient's understanding that participation in a survey and patient registry is required during the thalidomide treatment.

50. (New) The method of claim 49 further comprising providing the patient, prior to generation of the approval code, with warnings of the side effects associated with administration of thalidomide, wherein said side effects are non-teratogenic side effects.

51. (New) The method of claim 49 further comprising obtaining a written authorization by the prescriber prior to generation of the approval code.

52. (New) The method of claim 49 wherein the patient is required to use contraception for at least 4 weeks prior to generation of the approval code.

53. (New) The method of claim 49 wherein the patient is required to use contraception during thalidomide therapy.

54. (New) The method of claim 49 wherein the patient is required to use contraception for at least 4 weeks after discontinuation of thalidomide treatment.

REMARKS

Claims 1-30 have been canceled, and claims 31-54 have been added. Support for these claims can be found throughout the specification as originally filed. No new matter has been added. Consideration and allowance of the pending claims is respectfully requested.

Date: October 2, 2007

/Angela Verrecchio/
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Electronic Patent Application Fee Transmittal

Application Number:	11437551
Filing Date:	19-May-2006
Title of Invention:	Methods for delivering a drug to a patient while restricting access to the drug by patients for whom the drug may be contraindicated
First Named Inventor/Applicant Name:	Bruce A. Williams
Filer:	Angela Verrecchio/Joanne Gallagher
Attorney Docket Number:	CELG-0508

Filed as Large Entity

Utility Filing Fees

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Claims in excess of 20	1202	4	50	200
Independent claims in excess of 3	1201	2	210	420
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Extension-of-Time:				
Miscellaneous:				
		Total in USD ($)		**620**

Electronic Acknowledgement Receipt

EFS ID:	2270493
Application Number:	11437551
International Application Number:	
Confirmation Number:	3533
Title of Invention:	Methods for delivering a drug to a patient while restricting access to the drug by patients for whom the drug may be contraindicated
First Named Inventor/Applicant Name:	Bruce A. Williams
Customer Number:	23377
Filer:	Angela Verrecchio/Joanne Gallagher
Filer Authorized By:	Angela Verrecchio
Attorney Docket Number:	CELG-0508
Receipt Date:	02-OCT-2007
Filing Date:	19-MAY-2006
Time Stamp:	16:58:09
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment was successfully received in RAM	$620
RAM confirmation Number	2001
Deposit Account	233050
The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows: Charge any Additional Fees required under 37 C.F.R. Section 1.16 and 1.17	

File Listing:

Document Number	Document Description	File Name	File Size(Bytes) /Message Digest	Multi Part /.zip	Pages (if appl.)
1	Miscellaneous Incoming Letter	CELG-0508-transmittal.pdf	39329 bad4233fe7f9087802b45c73ba8d4d2c2e918049	no	4
Warnings:					
Information:					
2		CELG-0508-preliminaryamd.pdf	48837 8081ab27b0aabf2f4023665ab0a6951e5eecd5f8	yes	10

Multipart Description/PDF files in .zip description

Document Description	Start	End
Preliminary Amendment	1	1
Amendment Copy Claims/Response to Suggested Claims	2	9
Applicant Arguments/Remarks Made in an Amendment	10	10

Warnings:					
Information:					
3	Fee Worksheet (PTO-06)	fee-info.pdf	8356 346f972f4206ac5aa12004d787b33b6725af47e5	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	96522		

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111
If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371
If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office
If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

DOCKET NO.: CELG-0508 **PATENT**

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of:
Bruce a. Williams and Joseph K. Kaminski

Application No.: **11/437,551**

Filing Date: **May 19, 2006**

Confirmation No.: **3533**

Group Art Unit: **3626**

Examiner: **Lena Najarian**

For: **Methods For Delivering A Drug To A Patient While Restricting Access To The Drug By Patients For Whom The Drug May Be Contraindicated**

☒ MS Amendment ☐ MS AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

REPLY TRANSMITTAL LETTER

☒ A Preliminary Amendment.

☐ An Amendment Responsive to the Office Action Dated .

☐ An Amendment Supplemental to the Paper filed .

☐ A Substitute Specification (pages 1 -) in clean form.

☐ A substitute specification (pages 1 -) with markings.

☐ An Abstract is enclosed.

☐ replacement sheets of drawings are enclosed comprising figures .

☐ Request is hereby made to accept black and white photograph(s) in this case, as they are the only practicable medium for illustrating the claimed invention. One (1) set of black and white photographs comprising figure(s) is submitted herewith.

☐ Petition is hereby made to accept drawing(s)/photograph(s) in this case.

- ☐ Three (3) sets of color drawing(s)/photograph(s) and black and white photocopy that accurately depicts to the extent possible, the subject matter shown in the color drawing(s)/photograph(s), are enclosed, comprising figures .
- ☐ An amendment to the first paragraph in that portion of the Brief Description of the Drawings is also enclosed herewith advising that the patent contains at least one drawing/photograph in color.

☐ A Certified Copy of each of the following applications: is enclosed.

☐ An Assignee Power of Attorney is enclosed.

☐ Information Disclosure Statement.

- ☐ Attached Form 1449.
- ☐ A copy of each reference as listed on the attached Form PTO-1449 is enclosed herewith.

☐ A Terminal Disclaimer is attached.

☐ Appendices as follows: .

☐ Other

☐ **No Additional Fee is Due.**

☐ Applicant(s) has previously claimed small entity status under 37 CFR § 1.27.

☐ Applicant(s) by its/their undersigned attorney, claims small entity status under 37 CFR § 1.27 as .

☐ This application is no longer entitled to small entity status. It is requested that this be noted in the files of the U.S. Patent and Trademark Office.

DOCKET NO.: CELG-0508 **PATENT**

				SMALL ENTITY		NOT SMALL ENTITY	
	REMAINING AFTER AMENDMENT	HIGHEST PAID FOR	EXTRA	RATE	FEE	RATE	FEE
TOTAL CLAIMS	24	20	4	$25 EACH	$	$50 EACH	$200.00
INDEP. CLAIMS	5	3	2	$105 EACH	$	$210 EACH	$420.00
FIRST PRESENTATION OF MULTIPLE DEPENDENT				$185	$	$370	$0.00
☐ ONE MONTH EXTENSION OF TIME				$60	$	$120	$0.00
☐ TWO MONTH EXTENSION OF TIME				$230	$	$460	$0.00
☐ THREE MONTH EXTENSION OF TIME				$525	$	$1050	$0.00
☐ FOUR MONTH EXTENSION OF TIME				$820	$	$1640	$0.00
☐ FIVE MONTH EXTENSION OF TIME				$1115	$	$2230	$0.00
☐ LESS ANY EXTENSION FEE ALREADY PAID				minus	($)	minus	($0.00)
☐ TERMINAL DISCLAIMER				$65	**$**	$130	**$0.00**
☐ OTHER FEE OR SURCHARGE AS FOLLOWS:							
TOTAL FEE DUE					**$**		**$620.00**

☐ A check in the amount of **$ .00** is attached. Please charge any deficiency or credit any overpayment to Deposit Account 23-3050.

☒ Please charge Deposit Account No. 23-3050 in the amount of **$620.00**.

☒ The Commissioner is hereby authorized to charge any deficiency or credit any overpayment of the fees associated with this communication to Deposit Account No. 23-3050.

☐ Petition is hereby made under 37 CFR § 1.136(a) (fees: 37 CFR § 1.17(a)(1)-(4)) to extend the time for response to the Office Action of to and through comprising an extension of the shortened statutory period of month(s).

DOCKET NO.: CELG-0508 **PATENT**

☒ The Commissioner is hereby requested to grant an extension of time for the appropriate length of time, should one be necessary, in connection with this filing or any future filing submitted to the U.S. Patent and Trademark Office in the above-identified application during the pendency of this application. The Commissioner is further authorized to charge any fees related to any such extension of time to Deposit Account 23-3050.

Date: October 2, 2007

/Angela Verrecchio/
Angela Verrecchio
Registration No. 54,510

Woodcock Washburn LLP
Cira Centre
2929 Arch Street, 12th Floor
Philadelphia, PA 19104-2891
Telephone: (215) 568-3100
Facsimile: (215) 568-3439

PTO/SB/06 (12-04)
Approved for use through 7/31/2006. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

PATENT APPLICATION FEE DETERMINATION RECORD

Substitute for Form PTO-875 Effective December 8, 2004

Application or Docket Number: 11/437,551

APPLICATION AS FILED – PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA	SMALL ENTITY RATE ($)	SMALL ENTITY FEE ($)	OR	OTHER THAN SMALL ENTITY RATE ($)	OTHER THAN SMALL ENTITY FEE ($)
BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A	150.00		N/A	300.00
SEARCH FEE (37 CFR 1.16(k), (l), or (m))	N/A	N/A	N/A	$250		N/A	$500
EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A	$100		N/A	$200
TOTAL CLAIMS (37 CFR 1.16(i))	11 minus 20 = *		X$ 25 =		OR	X$50 =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	1 minus 3 = *		X100 =			X200 =	
APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $250 ($125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).						
MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))			+180=			+360=	
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL			TOTAL	1000

APPLICATION AS AMENDED – PART II

		(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	SMALL ENTITY RATE ($)	SMALL ENTITY ADDITIONAL FEE ($)	OR	OTHER THAN SMALL ENTITY RATE ($)	OTHER THAN SMALL ENTITY ADDITIONAL FEE ($)
AMENDMENT A	Total (37 CFR 1.16(i))	* 11	Minus	** 20	= *	X$ 25 =		OR	X$50 =	
	Independent (37 CFR 1.16(h))	* 1	Minus	*** 3	= *	X100 =		OR	X200 =	
	Application Size Fee (37 CFR 1.16(s))									
	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))					+180=		OR	+360=	
						TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	

10/2/07

		(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	SMALL ENTITY RATE ($)	SMALL ENTITY ADDITIONAL FEE ($)	OR	OTHER THAN SMALL ENTITY RATE ($)	OTHER THAN SMALL ENTITY ADDITIONAL FEE ($)
AMENDMENT B	Total (37 CFR 1.16(i))	* 24	Minus	** 20	= * 4	X$ 25 =		OR	X$50 =	200
	Independent (37 CFR 1.16(h))	* 5	Minus	*** 3	= * 2	X100 =		OR	X200 =	400
	Application Size Fee (37 CFR 1.16(s))									
	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))					+180=		OR	+360=	
						TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	600

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".
*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".
The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.

This collection of information is required by 37 CFR 1.16. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

PTO/SB/08a (05-07)
Approved for use through 09/30/2007. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	11437551
Filing Date	2006-05-19
First Named Inventor	Williams
Art Unit	3626
Examiner Name	Najarian, Lena
Attorney Docket Number	CELG-0508

U.S.PATENTS

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1					

If you wish to add additional U.S. Patent citation information please click the Add button.

U.S.PATENT APPLICATION PUBLICATIONS

Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	20060129433	A1	2006-06-15	Koneru	

If you wish to add additional U.S. Published Application citation information please click the Add button.

FOREIGN PATENT DOCUMENTS

Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2] ¡	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]
	1							☐

If you wish to add additional Foreign Patent Document citation information please click the Add button

NON-PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(**Not for submission under 37 CFR 1.99)**

Application Number	11437551
Filing Date	2006-05-19
First Named Inventor	Williams
Art Unit	3626
Examiner Name	Najarian, Lena
Attorney Docket Number	CELG-0508

	1	Notification letter dated 10/4/07 from Barr Laboratories to Celgene Corporation re: Supplemental Notification Pursuant to § 505(j)(2)(B)(ii) of the Federal Food, Drug and Cosmetic Act	☐

If you wish to add additional non-patent literature document citation information please click the Add button

EXAMINER SIGNATURE

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(**Not for submission under 37 CFR 1.99)**

Application Number	11437551
Filing Date	2006-05-19
First Named Inventor	Williams
Art Unit	3626
Examiner Name	Najarian, Lena
Attorney Docket Number	CELG-0508

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

☐ See attached certification statement.

☐ Fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ None

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/s/ Angela Verrecchio	Date (YYYY-MM-DD)	2007-11-26
Name/Print	Angela Verrecchio	Registration Number	54,510

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these record s.

2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Electronic Acknowledgement Receipt

EFS ID:	2508026
Application Number:	11437551
International Application Number:	
Confirmation Number:	3533
Title of Invention:	Methods for delivering a drug to a patient while restricting access to the drug by patients for whom the drug may be contraindicated
First Named Inventor/Applicant Name:	Bruce A. Williams
Customer Number:	23377
Filer:	Angela Verrecchio/Heather Kite
Filer Authorized By:	Angela Verrecchio
Attorney Docket Number:	CELG-0508
Receipt Date:	26-NOV-2007
Filing Date:	19-MAY-2006
Time Stamp:	16:34:10
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes) /Message Digest	Multi Part /.zip	Pages (if appl.)
1	Information Disclosure Statement (IDS) Filed	11-26-07_IDS.pdf	33304 f8c1a99c903be7695452b29f7c653c53f8054744	no	4

Warnings:	
Information:	

This is not an USPTO supplied IDS fillable form

2	NPL Documents	10-4-07_SuppNotif_ANDA78505.PDF	1531473 0389ade6ca40d083d6039531097 5f00dd15fbc86	no	27

Warnings:

Information:

Total Files Size (in bytes):	1564777

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111
If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371
If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office
If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

Interview Summary	Application No.	Applicant(s)	
	11/437,551	WILLIAMS ET AL.	
	Examiner	Art Unit	
	Michael Astorino	3736	

All participants (applicant, applicant's representative, PTO personnel):

(1) *Michael Astorino*.

(3) *Richard Thomas Girards, Jr.*.

(2) *Angela Verrecchio*.

(4)_____.

Date of Interview: *28 February 2008*.

Type: a)☐ Telephonic b)☐ Video Conference
c)☒ Personal [copy given to: 1)☐ applicant 2)☒ applicant's representative]

Exhibit shown or demonstration conducted: d)☐ Yes e)☒ No.
If Yes, brief description: _____.

Claim(s) discussed: *pending claims*.

Identification of prior art discussed: *N/A*.

Agreement with respect to the claims f)☐ was reached. g)☐ was not reached. h)☒ N/A.

Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: *The participants discussed the nature of the case with respect to the family of patents. This discussion was specific to the potential for obvious-type double patenting rejections*.

(A fuller description, if necessary, and a copy of the amendments which the examiner agreed would render the claims allowable, if available, must be attached. Also, where no copy of the amendments that would render the claims allowable is available, a summary thereof must be attached.)

THE FORMAL WRITTEN REPLY TO THE LAST OFFICE ACTION MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW. (See MPEP Section 713.04). If a reply to the last Office action has already been filed, APPLICANT IS GIVEN A NON-EXTENDABLE PERIOD OF THE LONGER OF ONE MONTH OR THIRTY DAYS FROM THIS INTERVIEW DATE, OR THE MAILING DATE OF THIS INTERVIEW SUMMARY FORM, WHICHEVER IS LATER, TO FILE A STATEMENT OF THE SUBSTANCE OF THE INTERVIEW. See Summary of Record of Interview requirements on reverse side or on attached sheet.

Examiner Note: You must sign this form unless it is an Attachment to a signed Office action.

Examiner's signature, if required

DOCKET NO.: CELG-0508 **PATENT**

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of:

Bruce A. Williams, et al. **Confirmation No.: 3533**

Application No.: 11/437,551 **Group Art Unit: 3736**

Filing Date: May 19, 2006 **Examiner: Michael C. Astorino**

For: METHODS FOR DELIVERING A DRUG TO A PATIENT WHILE RESTRICTING ACCESS TO THE DRUG BY PATIENTS FOR WHOM THE DRUG MAY BE CONTRAINDICATED

ELECTRONICALLY FILED:

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Pursuant to 37 CFR § 1.56 and in accordance with 37 CFR §§ 1.97-1.98, information relating to the above-identified application is hereby disclosed. Inclusion of information in this statement is not to be construed as an admission that this information is material as that term is defined in 37 CFR § 1.56(b).

☒ In accordance with § 1.97(b), since this Information Disclosure Statement is being filed either within three months of the filing date of the above-identified application, within three months of the date of entry into the national stage of the above identified application as set forth in § 1.491, before the mailing date of a first Office Action on the merits of the above-identified application, or before the mailing date of a first Office Action after the filing of request for continued examination under § 1.114, no additional fee is required.

☒ Copies of reference numbers 1 and 2 listed on the attached Form PTO-1449 are enclosed herewith.

☐ Copies of reference numbers - on the attached Form PTO 1449 are not required to be submitted pursuant to 37 CFR § 1.98(a)(2)(ii).

☐ Copies of references - are not being submitted because they were previously cited by or submitted to the U.S. Patent and Trademark Office in patent application number , filed for which a claim for priority under 35 U.S.C. § 120 has been made in the instant application.

There are no listed references which are not in the English language.

A complete copy of Reference number 1 (Uhl, K. et al., "Thalidomide Use in the US: Experience with Pregnancy Testing in the S.T.E.P.S.® Programme," *Drug Safety*, 2006, 29(4), 321-329) is submitted herewith to replace reference number 78 which was inadvertently submitted with missing pages in the Information Disclosure Statement filed by the Applicant on May 18, 2007.

Please charge any deficiency or credit any overpayment to Deposit Account No. 23-3050.

Date: April 22, 2008

/Angela Verrecchio/
Angela Verrecchio
Registration No. 54,510

WOODCOCK WASHBURN LLP
Cira Centre
2929 Arch Street, 12th Floor
Philadelphia, PA 19104-2891
Telephone: (215) 568-3100
Facsimile: (215) 568-3439

Form PTO-1449 Modified List of Patent and Publications Cited by Applicant (Use several sheets if necessary) U.S. Department of Commerce Patent and Trademark Office	Docket No. CELG-0508	Application No. 11/437,551
	Applicant Bruce A. Williams	
	Filing Date May 19, 2006	Group 3736
	Confirmation No. 3533	

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)		
	1	Uhl, K. et al., "Thalidomide Use in the US: Experience with Pregnancy Testing in the S.T.E.P.S.® Programme," *Drug Safety*, 2006, 29(4), 321-329
	2	Thalomid information from Drugs.com [online], Drugs.com, 22 June 2006 [retrieved on 2008-02-01], Retrieved from the internet: <URL: http://www.drugs.com/thalomid.html>

EXAMINER	**DATE CONSIDERED**

Electronic Acknowledgement Receipt

EFS ID:	3190294
Application Number:	11437551
International Application Number:	
Confirmation Number:	3533
Title of Invention:	Methods for delivering a drug to a patient while restricting access to the drug by patients for whom the drug may be contraindicated
First Named Inventor/Applicant Name:	Bruce A. Williams
Customer Number:	23377
Filer:	Angela Verrecchio/Heather Kite
Filer Authorized By:	Angela Verrecchio
Attorney Docket Number:	CELG-0508
Receipt Date:	22-APR-2008
Filing Date:	19-MAY-2006
Time Stamp:	15:24:14
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes) /Message Digest	Multi Part /.zip	Pages (if appl.)
1	NPL Documents	Uhl_DrugSafety_321-329.pdf	996945 ca9c582192b2354e5dbc23184bd8ddcfb1f78543	no	9

Warnings:	
Information:	

2	NPL Documents	Thalomid_webArticle.pdf	130518 ff81ad87c9843cb3c97a96c203bfd31ef9ccd42f	no	4
Warnings:					
Information:					
3	Information Disclosure Statement (IDS) Filed	SIDS_4-22-08.pdf	288492 69bed4a3c15325e37a7daf1b6b9837936ee9b7c6	no	3
Warnings:					
Information:					
This is not an USPTO supplied IDS fillable form					
			Total Files Size (in bytes):	1415955	

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111
If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371
If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office
If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/437,551	05/19/2006	Bruce A. Williams	CELG-0508	3533

23377 7590 05/01/2008

WOODCOCK WASHBURN LLP
CIRA CENTRE, 12TH FLOOR
2929 ARCH STREET
PHILADELPHIA, PA 19104-2891

EXAMINER	
ASTORINO, MICHAEL C	
ART UNIT	**PAPER NUMBER**
3736	
MAIL DATE	**DELIVERY MODE**
05/01/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	11/437,551	WILLIAMS ET AL.	
	Examiner	Art Unit	
	Michael Astorino	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 May 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *31-54* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *31-54* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *See Continuation Sheet*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :August 21, 2006, May 21, 2007, November 26, 2007, and April 22, 2008 .

DETAILED ACTION

Specification

The continuing data in the first paragraph of the specification needs to be updated.

The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which the applicant may become aware in the specification.

37 C.F.R. § 1.105

The examiner under 37 C.F.R. § 1.105 entitled, "Requirements for Information," requires a submission from the applicant information regarding the document in the letter dated October 4, 2007 from Barr Laboratories to Celgene Corporation re: Supplemental Notification Pursuant to § 505(j)(2)(B)(ii) of the Federal Food, Drug and Cosmetic Act. Specifically the reference entitled, Preventing Birth Defects Due to Thalidomide Exposure: Birth Defects and Genetic Diseases Branch, Centers of Disease Control and Prevention Public Meeting, Atlanta GA (March 26, 1997)."

Information Disclosure Statement

The information disclosure statement filed August 21, 2006, May 21, 2007, November 26, 2007, and April 22, 2008 complies with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609. It has been placed in the application file, the examiner's initials have been provided for

each citation, the document has been signed and dated, and the information referred to therein has been considered as to the merits.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 31-54 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the claims of U.S. Patent No.'s 6315720, 6561977, 6755784, 6869399, and 7141018. Although the conflicting claims are not identical, they are not patentably distinct from each other because it would have been obvious to one of ordinary skill

in the art at the time of the invention to implement the method of the patent in the manner set forth in the instant application since the claims of the instant application are merely broader renditions of the patented method.

Claims 31-54 are provisionally rejected under 35 U.S.C. 103(a) as being obvious over copending Application No. 11/104,013 which has a common Assignees with the instant application. Based upon the earlier effective U.S. filing date of the copending application, it would constitute prior art under 35 U.S.C. 102(e) if published or patented. This provisional rejection under 35 U.S.C. 103(a) is based upon a presumption of future publication or patenting of the conflicting application.

This provisional rejection might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the copending application was derived from the inventor of this application and is thus not the invention "by another," or by a showing of a date of invention for the instant application prior to the effective U.S. filing date of the copending application under 37 CFR 1.131. This rejection might also be overcome by showing that the copending application is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 31-54 are rejected under 35 U.S.C. 101. In order to be considered patent eligible under 35 USC 101, a claimed process must either result in a physical transformation or contain a

sufficient tie to a machine, article of manufacture or a composition of matter. *In re Comiskey,* 84 USPQ2d 1670 (Fed. Cir. 2007). In this case, the claimed invention does not transform any subject matter and has no tie to any machine, article of manufacture or a composition of matter. In this case, the independent claims 15, 22, 29, and 34 are directed to methods of treating male/female patients, yet the body of the claims fails to recite steps toward treating patients. Additionally a computer readable medium is not considered a sufficient tie in this case.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim(s) 31-54 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In this case, the independent claims 31, 32, 39, 46, and 49 are directed to methods of treating male/female patients, yet the body of the claims fails to recite steps toward treating patients. It is unclear to the examiner what steps are being taken to treat the patient because treatment steps are lacking from the claims. Additionally, Claim 31 recites no method steps. Otherwise stated, "permitting . . . ." is not a method step. It is the examiner's position that the broadest reasonable interpretation of the claimed invention is that no steps have been recited in the body of the claims regarding the treatment of the patient.

The Applicant is invited to respond to the examiner's interpretation of the claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 31-54 are rejected under 35 U.S.C. 102(a) as being anticipated by Transcript, Thalidomide: Potential Benefits and Risks, an open public scientific workshop, Sponsored by National Institutes of Health, Food and Drug Administration, Centers for Disease Control and Prevention, September 9, 1997. (Hereinafter Transcript)

The transcript provides, in part, the following recommendations and points regarding the use of Thalidmoide:

> "Patients should be suitable candidates for thalidomide. They should be educated and counseled about the teratogenicity, and about contraception. The drug should be packaged and dispensed in a manner to minimize both inappropriate and inadvertent use. Prescribers and dispensers should be well educated about thalidomide and its use. Patients should be monitored during use to reduce the risk for fetal exposure."
>
> Although we've received both positive and negative feedback about these suggestions on dispensing, the last two stimulated the most discussion, mainly pertaining to the idea that the pharmacist would also be a gatekeeper for thalidomide, and in some ways serve as the ultimate control over who receives the drug. This is not an idea without precedent. For at least one drug, Clozaril, dispensing cannot be done unless the pharmacist is presented documentation of requisite laboratory results.
>
> As an aside, it was encouraging to learn at the FDA meeting last Friday that Celgene will include the patient's diagnosis in their proposed registry, and would be able to monitor this data to limit inappropriate or trivial use of thalidomide.

It is the examiner position that the disclosure of the transcript is sufficient to reject the claimed invention considering the broadest reasonable interpretation of the claimed in invention as described above.

The Applicant is invited to request an interview to discuss suggestions to overcome the applied prior art and/or any other rejection, requirement, etc. in the office action.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Astorino whose telephone number is 571-272-4723. The examiner can normally be reached on Monday-Friday, 8:30AM to 3:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael Astorino/
Primary Examiner, Art Unit 3736

April 27, 2008

Notice of References Cited	Application/Control No. 11/437,551	Applicant(s)/Patent Under Reexamination WILLIAMS ET AL.	
	Examiner Michael Astorino	Art Unit 3736	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
	A	US-			
	B	US-			
	C	US-			
	D	US-			
	E	US-			
	F	US-			
	G	US-			
	H	US-			
	I	US-			
	J	US-			
	K	US-			
	L	US-			
	M	US-			

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
	N					
	O					
	P					
	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	Transcript, Thalidomide: Potential Benefits and Risks, an open public scientific workshop, Sponsored by National Institutes of Health, Food and Drug Administration, Centers for Disease Control and Prevention, September 9, 1997
	V	
	W	
	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	11437551	WILLIAMS ET AL.
	Examiner	Art Unit
	Michael Astorino	3736

SEARCHED

Class	Subclass	Date	Examiner
600	300-301	4/08	MA
128	920	4/08	MA
705	2-4	4/08	MA
235	375	4/08	MA

SEARCH NOTES

Search Notes	Date	Examiner
IDS	4/08	MA
See parent cases	4/08	MA
EAST Inventor Search	4/08	MA
STIC Search to Find sept 1997 Transcript	4/08	MA
Spoke with TQUAS(s) regarding 101 rejection	4/08	MA
West Search Timed out, lost class and text search	4/08	MA

INTERFERENCE SEARCH

Class	Subclass	Date	Examiner

654910

STIC
Scientific & Technical Information Center

REFERENCE DELIVERY REQUEST

Today's Date 4/9/08

Name Michael Astorino

AU/Org. 3736 Examiner # 74902

Phone X-2423

Bld., Rm. & Mailbox # RNB-7A39

Case/Application # 11/104013

Please attach the citation/abstract, or complete as much of the following as possible:

Author See Attached

Article or Chapter Title

Journal or Book Title

Volume and Issue #

Pages

Publication Date

ISSN/ISBN

Other Identifying Info.: Edition, PMID

Remarks Please see attached

Note to Examiner:
This is a transcript of a subsequent meeting held at NIH. On page 3 see the last speaker, Cynthia Moore, MD, PhD. Her comments are provided. I will still see if I can get a copy of the transcript for the March 26, 1997 meeting.

Please submit completed form to

STIC USE ONLY

Local Attempts	Date	Initials	Re
LC	4/9/08	AS	
Ordered from			
Source/date			

Miller, James (ASRC)

From: STIC-ILL
Sent: Wednesday, April 09, 2008 11:42 AM
To: Miller, James (ASRC)
Subject: FW: ILL-Astorino-11103013-20080409
Attachments: ILL-Astorino-11104013-20080409.pdf

wk

From: Suggs, Faye (ASRC)
Sent: Wednesday, April 09, 2008 11:40 AM
To: STIC-ILL
Subject: ILL-Astorino-11103013-20080409

Good Morning,

Please see the attached request. Thank you.

Faye Suggs (ASRC, MS)
Technical Information Specialist
EIC 3700
Reference Desk# (571) 272-4240
RND, 8B31

Email: STIC-EIC3700@uspto.gov

Detailed Factual and Legal Basis for BARR's Certification

I. Introduction

This document is the detailed factual and legal basis for the assertion of BARR LABORATORIES, INC. ("BARR") that, in its opinion and to the best of its knowledge, U.S. Patent Nos. 6,045,501 ("the '501 patent"); 6,315,720 ("the '720 patent"); 6,561,976 ("the '976 patent"); 6,561,977 ("the '977 patent"); 6,755,784 ("the '784 patent"); 6,869,399 ("the '399 patent"); 6,908,432 ("the '432 patent"); and 7,141,018 ("the '018 patent") are invalid, unenforceable or will not be infringed by the manufacture, use or sale of the drug products described in BARR's ANDA. The right to raise additional defenses is specifically reserved.

II. Background Information

A. Thalomid®

Thalomid® is an oral tablet formulation containing one of 50 mg, 100 mg, or 200 mg thalidomide. Pursuant to NDA No. 20-785, Thalomid® is approved for treating Erythema Nodosum Leprosum ("ENL").

B. The ANDA Formulation

The products that are the subject of BARR's ANDA No. 78-505 ("BARR's ANDA products") are generic versions of Thalomid®. BARR's ANDA products are oral tablet formulations containing 50 mg, 100 mg, or 200 mg of thalidomide. BARR's ANDA products will be marketed for the currently approved indication for Thalomid®, the acute treatment of the cutaneous manifestations of moderate to severe ENL.

III. Factual and Legal Basis For BARR's Certification

As discussed below, the claims of the '501, '720, '976, '977, '784, '399, '432, and '018 patents are invalid under 35 U.S.C. §§ 102 and/or 103 over the prior art, unenforceable, or will not be infringed by the manufacture, use, sale, offer for sale or importation of the drug products described in BARR's ANDA.

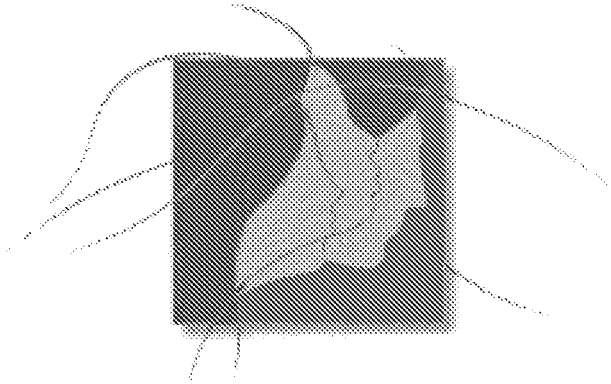
A. The Prior Art

1. Preventing Birth Defects Due to Thalidomide Exposure: Birth Defects and Genetic Diseases Branch, Centers for Disease Control and Prevention Public Meeting, Atlanta, GA (March 26, 1997)

A public meeting entitled "Preventing Birth Defects Due to Thalidomide Exposure: Birth Defects and Genetic Diseases Branch, Centers for Disease Control and Prevention" was held on March 26, 1997 in Atlanta, GA. A trancript of the meeting ("the CDC transcript") was made publicly available 4-6 weeks after the meeting took place. Thus, the CDC transcript qualifies as prior art to each of the '501, '720, '976, '977, '784, '399, '432, and '018 patents under 35 U.S.C. § 102(b) as it was publicly available more than one year prior to the earliest priority date of the '501, '720, '976, '977, '784, '399, '432, and '018 patents.

U.S. Food and Drug Administration

THALIDOMIDE: POTENTIAL BENEFITS AND RISKS



AN OPEN PUBLIC SCIENTIFIC WORKSHOP
September 9-10, 1997

Natcher Conference Center - National Institutes of Health - Bethesda, Maryland

TRANSCRIPT

THALIDOMIDE: POTENTIAL BENEFITS AND RISK

OPEN PUBLIC SCIENTIFIC WORKSHOP

Sponsored By

NATIONAL INSTITUTES OF HEALTH

FOOD AND DRUG ADMINISTRATION

CENTERS FOR DISEASE CONTROL AND PREVENTION

Tuesday, September 9, 1997

Auditorium
Natcher Conference Center
National Institutes of Health
9000 Rockville Pike
Bethesda, Maryland

C O N T E N T S
(with hyperlinks to speakers presentations)

OPENING REMARKS AND OVERVIEW

Stephen C. Groft, Pharm.D., Moderator
Director, Office of Rare Diseases, NIH

Opening Remarks and Introductions
Stephen C. Groft Pharm.D. Introduction,
Stephen C. Groft Pharm.D. Opening Remarks

Welcome
William R. Harlen, M.D.
Associate Director for Disease Prevention, NIH

Historical Perspective
Frances O. Kelsey, M.D.
Deputy for Scientific Affairs
Office of Compliance, FDA

Current Issues and Overview
Janet Woodcock, M.D.
Director, Center for Drug Evaluation and Research, FDA

Experience with Thalidomide in Mexico
Guillermo Bierzwinsky, M.D.
Director, Drug Control Directorate of Mexico

National Center for Toxicological Research, FDA

Monitoring for Peripheral Neuropathy
Mary K. Floeter, M.D., Ph.D.
National Institute of Neurological Disorders and Stroke, NIH

Questions

PREGNANCY/EMBRYOPATHY

James Mills, M.D., Moderator
National Institute of Child Health and Human Development, NIH

Characterization of Embryopathy Risks
Barbara A. Hill, Ph.D.
Division of Dermatological and Dental Drug Products
Center for Drug Evaluation and Research, FDA

Pregnancy Prevention in Patients Taking Thalidomide
Christine K. Mauck, M.D., M.P.H.
Division of Reproductive and Urologic Drug Products
Center for Drug Evaluation and Research, FDA

How Environmental Effects on Child Health Are Recognized
Robert W. Miller, M.D., Dr.P.H.
National Cancer Institute, NIH

Experience With Accutane
Allen A. Mitchell, M.D.
Boston University

Preventing Birth Defects Due to Thalidomide Exposure
Cynthia Moore, M.D., Ph.D.
Centers for Disease Control and Prevention

Questions

you'll pardon me, which offers a likelihood of cure, in contrast to other anti-acne therapies, and there's a short duration of therapy.

Is the experience with Accutane applicable to other human teratogens? Well, I basically listed the characteristics for Accutane, and I think it's the task of all of us to worry about whether this has any applicability to thalidomide.

Finally, while this experience suggests that the PPP for Accutane is effective, it's unclear whether the same program would be similarly effective for other therapeutic teratogens.

Thank you.

(Applause.)

DR. MILLS: Thank you.

Our last speaker today is **Dr. Cynthia Moore**, who is the acting deputy chief of the Birth Defects and Genetic Diseases Branch at the CDC. She is going to provide a summary and recommendations based on preventing birth defects due to thalidomide exposure and the CDC meeting.

DR. MOORE: I'm happy to have this opportunity to speak with you today and participate in this meeting as the last speaker, because in essence that gives me the final word today, and that's a situation I always like.

I also participated in the FDA meeting last week, and I gave this presentation. I wanted to point out, especially for those of you who weren't at that meeting, that, although the FDA advisory committee did vote for approval of thalidomide, saying the benefits were greater than the risks, they also voted that all the safety issues have not been adequately described.

The Centers for Disease Control and Prevention entered this arena because a major part of the Division of Birth Defects and Developmental Disabilities' mission is to improve the health of American children by preventing birth defects. To a great extent, our division owes its existence to the tragedy that was the first thalidomide epidemic, and we as well as others do not wish to see a second epidemic occur.

In March of this year, CDC sponsored a workshop in Atlanta entitled "Preventing Birth Defects Due to Thalidomide Exposure." We were fortunate to have the participation by

individuals from many different areas of expertise, including our federal colleagues from the FDA, the NIH, many pharmaceutical companies, professional practice representatives, academicians, and others. The purpose of this meeting was to provide a forum devoted to the discussion of the teratogenic effects of thalidomide, and methods to limit fetal exposure to this drug, should it be approved for use. This meeting was not designed to develop a consensus on this issue, and no attempt was made to reach one, but merely to gather individual suggestions by meeting participants.

Although other adverse effects of this drug are known or suspected, the CDC meeting addressed only the teratogenic effects. I believe that we are all well aware of these birth defects. We've heard from several presenters today that we know when this drug is used by women of childbearing potential, the risk for causing serious birth defects can never be lowered to zero.

In situations where there is indiscriminate use of the drug, or poor control surrounding its use, as in Brazil, infants with thalidomide embryopathy are being born. This is an infant born in 1994 to a Brazilian mother who received thalidomide for treatment for leprosy. He has the typical malformations associated with thalidomide exposure.

I'd like to comment, kind of in response to Dr. Hill's presentation, that one of the problems that was pointed out in Dr. Castilla's report of these Brazilian infants was that we had typically characterized the limb deficiencies as phocomelia, even though other authors had described the preaxial or radial ray defects. In the small group that Dr. Castilla reported -- and this is one of those babies -- the incidence of preaxial defects was about half of the infants, which I think were 11 children.

This presents a difficulty in surveillance systems because, although phocomelia has very few causes, especially bilateral phocomelia, there are many causes for bilateral radial agenesis.

So who is at risk in the United States if thalidomide is approved for use by the FDA for ENL? Is it individuals with ENL? We've been told that there are currently five patients at the Hansen's Disease Center in Carville, Louisiana, who are receiving thalidomide for treatment of ENL. Four of these patients are male. The numbers of individuals with ENL in the other parts of the United States also appears to be small.

The risk for individuals who have been buying thalidomide through buyers clubs may be

low, since I understand most of these individuals are male. At least in Atlanta this is true, where we were recently told that the membership was 91 percent male.

The CDC meeting participants considered, not only the teratogenic risks for individuals with ENL, but also the risks that this approval will bring to a population of patients with other disorders for which treatment with thalidomide has given beneficial results, and those who may receive it through indiscriminate use. We did not have an opportunity to discuss risks that will occur if this drug is ever used as a drug of abuse.

There isn't time to present every one of the dozens of suggestions we heard at the March meeting. Our staff considered all of them, and extracted those which we thought would be most effective and practical in preventing fetal exposure.

In the form of draft recommendations, these suggestions have gone out for comment to meeting participants and the members of the Thalidomide Interagency Working Group. They are now under revision by CDC staff. I'd like to highlight some of these suggestions this afternoon.

We noted that virtually all of the suggestions to prevent birth defects centered around the concepts of limiting the use of the drug, educating health care providers and patients about the use of the drug, and monitoring those who are using the drug.

These concepts were summarized by CDC staff into these five proposed recommendations focused mainly on women of childbearing potential. They are as follows. Patients should be suitable candidates for thalidomide. They should be educated and counseled about the teratogenicity, and about contraception. The drug should be packaged and dispensed in a manner to minimize both inappropriate and inadvertent use. Prescribers and dispensers should be well educated about thalidomide and its use. Patients should be monitored during use to reduce the risk for fetal exposure.

When considering if a woman of childbearing potential is a suitable candidate for thalidomide therapy, we thought these four points were very important. The most difficult issue has been the first point listed, for it seems that most would agree with the other points, that a prospective patient should not be pregnant at the initiation of therapy; should have access to and be a capable and effective user of birth control; and should understand the risks associated with using this drug.

However, when to use the drug is the question. It was also suggested at the meeting that the drug should have not only been proven to be effective for the condition, but because of the severe risk, other options, hopefully nonteratogenic, should have been tried first, if they are available.

Since approval of a drug for a specific use must be based in part on its effectiveness, it was suggested by some meeting participants that the common practice of off-label use of drugs be prohibited for thalidomide, to prevent the indiscriminate use for disorders for which thalidomide has not been found to be effective in rigorous trials. Again, the suggestion to prohibit off-label use is controversial, but it would limit exposure, at least until other indications are approved.

Patients should of course be counseled about the teratogenicity. In all patient education activities, the concepts of appropriate and pretested messages with post-educational knowledge assessment are included. Several meeting participants stressed the need for inclusion of photographs of affected infants. The line drawing of an infant with Accutane embryopathy that's included in the Roche pregnancy prevention program was thought to be inadequate.

Also, avoiding possible fetal exposure caused by sharing pills, or taking leftover pills, necessitates counseling all patients about the teratogenicity and the importance of not keeping unused pills.

The choice of an effective contraceptive approach, particularly for individuals with chronic illness, can be challenging, according to our OB/GYN colleagues. For example, we were given, as one example, that IUDs are probably not a good idea in women with HIV infection. It was suggested that this practice of prescribing contraceptives be limited to those providers who have expertise in this area.

Although consistent and proper use of contraception is a goal, unprotected intercourse could occur under a number of circumstances. This topic also elicited many comments from our meeting participants, since we proposed that emergency contraception be discussed and prescribed. At the very least, as one of our participants suggested, female patients of childbearing potential who have unprotected sexual intercourse should stop taking thalidomide immediately, and not resume until they are evaluated and found not to be pregnant.

This same suggestion would apply to women who are uncertain about the effectiveness of their contraception at any point in time. The last approach would necessitate that we have reliable data on the elimination of thalidomide from the body, however.

Packaging suggestions included labels that state, "Causes severe birth defects," and the word "thalidomide." How recognizable the word "thalidomide" is to individuals in their 20s and 30s, who may be patients or even health care providers, is not known to us, although some preliminary data from the FDA indicates that at least 50 percent of individuals do not recognize the name.

Other ideas, such as blister packs, and use of a tested symbol to denote no use in pregnancy were also discussed during the meeting.

Although we've received both positive and negative feedback about these suggestions on dispensing, the last two stimulated the most discussion, mainly pertaining to the idea that the pharmacist would also be a gatekeeper for thalidomide, and in some ways serve as the ultimate control over who receives the drug. This is not an idea without precedent. For at least one drug, Clozaril, dispensing cannot be done unless the pharmacist is presented documentation of requisite laboratory results.

The most notable point under this heading is the suggested concept that prescribers and dispensers should do more than just register to obtain the privilege. Education and knowledge assessment should be connected to this privilege, a privilege which also could be revoked. The development of specific practice guidelines by professional groups was also suggested.

Monitoring suggestions pertaining to follow-up of the female patient while on therapy by her health care provider, and referral for specialized counseling in the event of exposed pregnancy, were also suggested. In addition, a more global monitoring of all women of childbearing potential through the establishment of a prospective, consolidated, and multi-company registry was suggested.

This registry would follow all women of childbearing potential on thalidomide for fetal exposure and outcome of exposed pregnancies. The registry would provide information to determine the magnitude, and hopefully the source, of prevention failures.

As an aside, it was encouraging to learn at the FDA meeting last Friday that Celgene will

include the patient's diagnosis in their proposed registry, and would be able to monitor this data to limit inappropriate or trivial use of thalidomide.

That's the last slide, so I can have the lights up.

I've given a brief overview of the suggestions from the CDC meeting, "Preventing Birth Defects Due to Thalidomide Exposure." As an encompassing summary, we were told that the most rigorous pregnancy prevention program yet established, the Roche pregnancy prevention program for women on Accutane, was a good starting point, but was not rigorous enough for a teratogen as potent as thalidomide.

Evaluation of this program has shown that some women received Accutane without a pregnancy test. Pregnancies did occur during therapy, and effective pregnancies were aborted, or went on to live birth.

Unfortunately, even with a stronger program for thalidomide, some affected infants will be born.

I'd like to thank all the participants of our March meeting, and those who gave us feedback on those draft recommendations. Our Birth Defects Branch at CDC is eager to further explore suggestions from our meeting, and work with all parties to develop a prevention program that hopefully will assist women who receive thalidomide, their partners, and their health care providers in preventing these serious, but preventable, birth defects.

The desire for a healthy baby is nearly universal. In my clinical experience, that desire is intensified in women who battle a chronic disease during pregnancy. Regardless of how long it takes, I believe we owe all women our best efforts to try to make this desire a reality.

Thank you.

(Applause.)

DR. MILLS: I'd like to thank all of our excellent speakers for what were uniformly well thought out and well presented talks.

I'll invite you all to come to the microphones for questions, and while you're flocking down to the microphones, I was asked by Steve to mention that we start at 8:00 tomorrow.

Transcript Prepared by: Freilicher & Associates, Court Reporters, 12309 Village Square Terrace, Suite 101, Rockville, Maryland 20852

HTML coding by: Office of Special Health Issues, FDA June 29, 1998

Placed on the FDA Web on July 16, 1998

Return to Patient Involvement Index

National Institutes of Health Office of Rare Diseases

EAST Search History

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L1	182	((BRUCE) near2 (WILLIAMS)).INV.	US-PGPUB; USPAT	OR	OFF	2008/04/27 15:40
L2	47	((JOSEPH) near2 (KAMINSKI)).INV.	US-PGPUB; USPAT	OR	OFF	2008/04/27 15:41
L3	151	l1 l2	USPAT	OR	OFF	2008/04/27 15:41
L4	9	l3 and thalid$	USPAT	OR	OFF	2008/04/27 15:41

4/27/08 3:41:44 PM

Sheet 1 of 1

Form PTO-1449 Modified List of Patent and Publications Cited by Applicant (Use several sheets if necessary) U.S. Department of Commerce Patent and Trademark Office	Docket No. CELG-0508	Application No. 11/437,551
	Applicant Bruce A. Williams	
	Filing Date May 19, 2006	Group 3736
	Confirmation No. 3533	

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)		
	1	Uhl, K. et al., "Thalidomide Use in the US: Experience with Pregnancy Testing in the S.T.E.P.S.® Programme," *Drug Safety*, 2006, 29(4), 321-329
	2	Thalomid information from Drugs.com [onlinc], Drugs.com, 22 Junc 2006 [rctricvcd on 2008-02-01], Retrieved from the internet: <URL: http://www.drugs.com/thalomid.html>

EXAMINER	/Michael Astorino/	DATE CONSIDERED	04/27/2008

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	Confirmation No. 3533	

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	57	5,758,095	05/26/98	Albaum et al.	395	202

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EXAMINER	DATE CONSIDERED

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Form PTO-1449 Modified List of Patent and Publications Cited by Applicant (Use several sheets if necessary) U.S. Department of Commerce Patent and Trademark Office	Docket No. CELG-0508	Application No. 11/437,551
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	81	Defendant Barr Laboratories, Inc.'s Answer, Counterclaims and Demand for Jury Trial filed 3/01/2007 in NJ: *Celgene Corp. v. Barr Laboratories*, Case No. 2:07-cv-00286-PGS-RJH
	82	Fax sent 10/14/04 from Ian Hilley of GenPharm, Inc. to John Jackson of Celgene Corp. re: Isotretinoin Pregnancy Risk Management Program
	83	Press Release dated 11/23/04, "Isotretinoin Makers Reach Agreement with Celgene on S.T.E.P.S. Risk Management Patents,"
	84	Notification letter dated 12/5/06 from Sterne Kessler to Celgene Corporation re: Notification Pursuant to § 505(j)(2)(B)(ii) of the Federal Food, Drug and Cosmetic Act
	85	Notification letter dated 12/15/06 from Sterne Kessler to Celgene Corporation re: Supplemental Notification Pursuant to § 505(j)(2)(B)(ii) of the Federal Food, Drug and Cosmetic Act
	86	Notification letter dated 12/19/06 from Sterne Kessler to Celgene Corporation re: Supplemental Notification Pursuant to § 505(j)(2)(B)(ii) of the Federal Food, Drug and Cosmetic Act

EXAMINER	/Michael Astorino/	**DATE CONSIDERED**	04/27/2008

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Form PTO-1449 Modified

List of Patent and Publications
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Patent and Trademark Office

Docket No. CELG-0508	Application No. 11/437,551
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EXAMINER	/Michael Astorino/	DATE CONSIDERED	04/27/2008

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EXAMINER	/Michael Astorino/	DATE CONSIDERED	04/27/2008

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EXAMINER /Michael Astorino/	**DATE CONSIDERED** 04/27/2008

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	Filing Date May 19, 2006	Group 3736
	Confirmation No. 3533	

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PTO/SB/08a (05-07)
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	11437551
Filing Date	2006-05-19
First Named Inventor	Williams
Art Unit	3626
Examiner Name	Najarian, Lena
Attorney Docket Number	CELG-0508

U.S.PATENTS

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1					

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U.S.PATENT APPLICATION PUBLICATIONS

Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	20060129433	A1	2006-06-15	Koneru	

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	1							☐

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NON-PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(**Not for submission under 37 CFR 1.99)**

Application Number	11437551
Filing Date	2006-05-19
First Named Inventor	Williams
Art Unit	3626
Examiner Name	Najarian, Lena
Attorney Docket Number	CELG-0508

	1	Notification letter dated 10/4/07 from Barr Laboratories to Celgene Corporation re: Supplemental Notification Pursuant to § 505(j)(2)(B)(ii) of the Federal Food, Drug and Cosmetic Act	☐

If you wish to add additional non-patent literature document citation information please click the Add button

EXAMINER SIGNATURE

Examiner Signature	/Michael Astorino/	Date Considered	04/27/2008

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

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DOCKET NO.: CELG-0508 **PATENT**
Application No.: 11/437,551
Office Action Dated: May 1, 2008

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:
Bruce A. Williams and Joseph K. Kaminski

Confirmation No.: **3533**

Application No.: **11/437,551**

Group Art Unit: **3736**

Filing Date: **May 19, 2006**

Examiner: **Michael C. Astorino**

For: **Methods For Delivering A Drug To A Patient While Restricting Access To The Drug By Patients For Whom The Drug May Be Contraindicated**

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

REPLY PURSUANT TO 37 CFR § 1.111

In response to the Official Action dated **May 1, 2008**, reconsideration is respectfully requested in view of the amendments and/or remarks as indicated below:

☒ **Amendments to the Specification** begin on page 2 of this paper.

☒ **Amendments to the Claims** are reflected in the listing of the claims which begins on page 3 of this paper.

☐ **Amendments to the Drawings** begin on page of this paper and include an attached replacement sheet.

☒ **Remarks** begin on page 11 of this paper.

Amendments to Specification

On page 1, please delete the paragraph immediately after "CROSS REFERENCE TO RELATED APPLICATIONS" and replace with the following:

This application is a continuation of U.S. Application Serial No. 11/028,144, filed January 3, 2005, now U.S. Patent 7,141,018, which is a continuation of U.S. Application Serial No. 10/762,880, filed January 22, 2004, now U.S. Patent No. 6,869,399, which is a continuation of U.S. Application Serial No. 10/383,275, filed March 7, 2003, now U.S. Pat. No. 6,755,784, which is a continuation of U.S. Application Serial No. 09/965,155, filed September 27, 2001, now U.S. Pat. No. 6,561,977, which is a continuation of U.S. Application No. 09/694,217, filed October 23, 2000, now U.S. Pat. No. 6,315,720, the entirety of each of which is hereby incorporated by reference.

This listing of claims will replace all prior versions, and listings, of claims in the application.

Listing of Claims:

Claims 1-30 (Canceled).

31. (Currently Amended) A method of treating a patient, suffering from erythema nodosum leprosum, with thalidomide, said method comprising (a) permitting prescriptions for thalidomide to be filled by a pharmacy only after the pharmacy has retrieved an approval code for the prescription from a computer readable medium and (b) administering thalidomide to the patient.

32. (Currently Amended) A method of treating a male patient, suffering from erythema nodosum leprosum, with thalidomide, said method comprising (a) permitting prescriptions for thalidomide to be filled by a pharmacy only after the pharmacy has retrieved an approval code for the prescription and (b) administering thalidomide to the patient, wherein the generation of the prescription approval code comprises the following steps:

(1~~a~~) registering a prescriber and the pharmacy with a distributor of thalidomide;

(2~~b~~) determining whether the patient is able to understand and reliably carry out instructions;

(3~~c~~) upon determination that the patient is able to carry out the instructions, providing oral and written warnings of the hazard of taking thalidomide and exposing fetus to the drug;

(4~~d~~) further providing oral and written warnings of the risk of possible contraception failure and of the need to use barrier contraception when having sexual intercourse with women of child bearing potential;

(5~~e~~) obtaining acknowledgement of said warnings from the patient;

(6~~f~~) registering the patient with the distributor; and

(7~~g~~) upon obtaining the acknowledgement and registration, generating the prescription approval code to be retrieved by the pharmacy before the prescription is filled.

33. (Previously Presented) The method of claim 32, wherein the acknowledgement requires the patient's acknowledgement of one or more of the following:

(a) the understanding that thalidomide must not be taken if unprotected sex cannot be avoided;

(b) the understanding of potential birth defects;

(c) that the patient has been advised of the need for barrier contraception by the prescriber;

(d) the obligation to inform the prescriber if the patient's sexual partner is suspected of becoming or being pregnant;

(e) that thalidomide is solely for the use of the patient himself and must not be shared with any other person;

(f) that the patient has read the information brochure or viewed the information film on thalidomide;

(g) that the semen or blood must not be donated during the thalidomide treatment;

(h) that all of the patient's inquiries regarding thalidomide treatment have been answered by the prescribing physician; or

(i) the patient's understanding that participation in a survey and patient registry is required during the thalidomide treatment.

34. (Previously Presented) The method of claim 32 further comprising providing the patient, prior to generation of the approval code, with warnings of the side effects associated with administration of thalidomide, wherein said side effects are non-teratogenic side effects.

35. (Previously Presented) The method of claim 32 further comprising obtaining a written authorization by the prescriber prior to generation of the approval code.

36. (Previously Presented) The method of claim 32, wherein the prescription approval code is retrieved from a computer readable storage medium.

37. (Previously Presented) The method of claim 32, wherein the acknowledgement is a written informed consent.

38. (Previously Presented) The method of claim 37, wherein the written informed consent is registered in the medium prior to generation of the prescription approval code.

39. (Currently Amended) A method of treating a female patient, suffering from erythema nodosum leprosum, with thalidomide, said method comprising (a) permitting prescriptions for thalidomide to be filled by a pharmacy only after the pharmacy has retrieved an approval code for the prescription and (b) administering thalidomide to the patient, wherein the generation of the prescription approval code comprises the following steps:

(1~~a~~) registering a prescriber and the pharmacy with a distributor of thalidomide;

(2~~b~~) determining whether the patient is able to understand and reliably carry out instructions;

(3~~c~~) upon determination that the patient is able to carry out the instructions, determining whether the patient is of child bearing potential;

(4~~d~~) upon determining that the patient is of child bearing potential, providing oral and written warnings of the hazard of taking thalidomide and exposing fetus to the drug;

(5~~e~~) further providing oral and written warnings of the risk of possible contraception failure and of the need to simultaneous use of two reliable forms of contraception;

(6~~f~~) obtaining acknowledge of said warnings from the patient;

(7~~g~~) determining, prior to the scheduled beginning of the thalidomide therapy, whether the patient is pregnant;

(8~~h~~) registering the patient with the distributor; and

(9~~i~~) generating the prescription approval code to be retrieved by the pharmacy before the prescription is filled.

40. (Previously Presented) The method of claim 39, wherein the acknowledgement requires the patient's acknowledgement of one or more of the following:

(a) the understanding that thalidomide must not be taken if the patient is pregnant, breastfeeding a baby, or able to get pregnant and not using birth controls;

(b) the understanding of potential birth defects;

(c) the warning received by the prescriber regarding said birth defects;

(d) the understanding of the need for at least two forms of contraception prior to, during, and subsequent to thalidomide treatment;

(e) the obligation to undergo a pregnancy test prior to starting thalidomide treatment;

(f) the obligation to undergo a pregnancy test during the thalidomide treatment;

(g) the obligation to discontinue thalidomide treatment and inform theprescriber in the case that the patient is suspected of becoming or being pregnant;

(h) that the patient is not currently pregnant and will not try to become pregnant for at least 4 weeks after the completion of thalidomide treatment;

(i) that thalidomide is solely for the use of the patient herself and must not be shared with any other person;

(j) that the patient has read the information brochure or viewed the information film on thalidomide;

(k) that the blood must not be donated during the thalidomide treatment;

(l) that all of the patient's inquiries regarding thalidomide treatment have been answered by the prescriber; or

(m) the patient's understanding that participation in a survey and patient registry is required during the thalidomide treatment.

41. (Previously Presented) The method of claim 39 further comprising providing the patient, prior to generation of the approval code, with warnings of the side effects associated with administration of thalidomide, wherein said side effects are non-teratogenic side effects.

42. (Previously Presented) The method of claim 39 further comprising obtaining a written authorization by the prescriber prior to generation of the approval code.

43. (Previously Presented) The method of claim 39, wherein the prescription approval code is retrieved from a computer readable storage medium.

44. (Previously Presented) The method of claim 39, wherein the acknowledgement is a written informed consent.

45. (Previously Presented) The method of claim 44, wherein the informed written consent is registered in the medium prior to generation of the prescription approval code.

46. (Currently Amended) A method of treating a male patient, suffering from erythema nodosum leprosum, with thalidomide, said method comprising (a) permitting prescriptions for thalidomide to be filled by a pharmacy only after the pharmacy has retrieved an approval code for the prescription from a computer readable storage medium and (b) administering thalidomide to the patient, wherein the generation of the prescription approval code comprises the following steps:

(1~~A~~) registering a prescriber and the pharmacy in the computer readable storage medium;

(2~~B~~) determining whether the patient is able to understand and reliably carry out instructions;

(3~~C~~) upon determination that the patient is able to carry out instructions, providing oral and written warnings of the hazard of taking thalidomide and exposing fetus to the drug;

(4~~D~~) further providing oral and written warnings of the risk of possible contraception failure and of the need to use barrier contraception when having sexual intercourse with women of child bearing potential;

(5~~E~~) obtaining informed consent from the patient;

(6~~F~~) registering the patient in the computer readable storage medium; ~~and~~

(7~~G~~) upon obtaining the informed consent and registration, generating the prescription approval code to be retrieved by the pharmacy before the prescription is filled, wherein said informed consent requires the patient's acknowledgement of one or more of the following:

~~(a)~~ the understanding that thalidomide must not be taken if unprotected sex cannot be avoided;

~~(b)~~ the understanding of potential birth defects;

~~(c)~~ that the patient has been advised of the need for barrier contraception by the prescriber;

~~(d)~~ the obligation to inform the prescriber if the patient's sexual partner is suspected of becoming or being pregnant;

~~(e)~~ that thalidomide is solely for the use of the patient himself and must not be shared with any other person;

~~(f)~~ that the patient has read the information brochure or viewed the information film on thalidomide;

~~(g)~~ that the semen or blood must not be donated during the thalidomide treatment;

~~(h)~~ that all of the patient's inquiries regarding thalidomide treatment have been answered by the prescribing physician; and ~~or~~

~~(i)~~ the patient's understanding that participation in a survey and patient registry is required during the thalidomide treatment.

47. (Previously Presented) The method of claim 46 further comprising providing the patient, prior to generation of the approval code, with warnings of the side effects associated with administration of thalidomide, wherein said side effects are non-teratogenic side effects.

48. (Previously Presented) The method of claim 46 further comprising obtaining a written authorization by the prescriber prior to generation of the approval code.

49. (Currently Amended) A method of treating a female patient, suffering from erythema nodosum leprosum, with thalidomide, said method comprising (a) permitting prescriptions for thalidomide to be filled by a pharmacy only after the pharmacy has retrieved an approval code for the prescription from a computer readable storage medium and (b) administering thalidomide to the patient, wherein the generation of the prescription approval code comprises the following steps:

(1~~A~~) registering a prescriber and the pharmacy in the computer readable storage medium;

(2~~B~~) determining whether the patient is able to understand and reliably carry out instructions;

(3~~C~~) upon determination that the patient is able to carry out instructions, determining whether the patient is of child bearing potential;

(4~~D~~) upon determining that the patient is of child bearing potential, providing oral and written warnings of the hazard of taking thalidomide and exposing fetus to the drug;

(5~~E~~) further providing oral and written warnings of the risk of possible contraception failure and of the need to simultaneous use of two reliable forms of contraception;

(6~~F~~) obtaining informed consent from the patient;

(7~~G~~) determining, prior to the scheduled beginning of the thalidomide therapy, whether the patient is pregnant;

(8~~H~~) registering the patient in the computer readable storage medium; ~~and~~

(9~~I~~) generating the prescription approval code to be retrieved by the pharmacy before the prescription is filled; and wherein said informed consent requires the patient's acknowledgement of one or more of the following:

~~(a)~~ the understanding that thalidomide must not be taken if the patient is pregnant, breastfeeding a baby, or able to get pregnant and not using birth controls;

~~(b)~~ the understanding of potential birth defects;

~~(c)~~ the warning received by the prescriber regarding said birth defects;

~~(d)~~ the understanding of the need for at least two forms of contraception prior to, during, and subsequent to thalidomide treatment;

~~(e)~~ the obligation to undergo a pregnancy test prior to starting thalidomide treatment;

~~(f)~~ the obligation to undergo a pregnancy test during the thalidomide treatment;

~~(g)~~ the obligation to discontinue thalidomide treatment and inform the prescriber in the case that the patient is suspected of becoming or being pregnant;

~~(h)~~ that the patient is not currently pregnant and will not try to become pregnant for at least 4 weeks after the completion of thalidomide treatment;

~~(i)~~ that thalidomide is solely for the use of the patient herself and must not be shared with any other person;

~~(j)~~ that the patient has read the information brochure or viewed the information film on thalidomide;

~~(k)~~ that the blood must not be donated during the thalidomide treatment~~.~~;

~~(l)~~ that all of the patient's inquiries regarding thalidomide treatment have been answered by the prescriber; and ~~or~~

~~(m)~~ the patient's understanding that participation in a survey and patient registry is required during the thalidomide treatment.

50. (Previously Presented) The method of claim 49 further comprising providing the patient, prior to generation of the approval code, with warnings of the side effects associated with administration of thalidomide, wherein said side effects are non-teratogenic side effects.

51. (Previously Presented) The method of claim 49 further comprising obtaining a written authorization by the prescriber prior to generation of the approval code.

52. (Previously Presented) The method of claim 49 wherein the patient is required to use contraception for at least 4 weeks prior to generation of the approval code.

53. (Previously Presented) The method of claim 49 wherein the patient is required to use contraception during thalidomide therapy.

54. (Previously Presented) The method of claim 49 wherein the patient is required to use contraception for at least 4 weeks after discontinuation of thalidomide treatment.

REMARKS

Claims 31-54 are currently pending. Claims 31, 32, 39, 46, and 49 have been amended.

Applicants wish to thank the Examiner for extending them the courtesy of an interview on February 28, 2008. At that interview, the continuity history of the pending application was summarized and the potential for encountering obviousness-type double patenting issues was addressed.

Specification

As requested by the Action at 2, the specification has been amended to update the continuing data.

37 C.F.R. § 1.105

The examiner has requested that the Applicants submit a copy of a reference allegedly entitled "Preventing Birth Defects Due to Thalidomide Exposure: Birth Defects and Genetic Diseases Branch, Centers of Disease Control and Prevention Public Meeting, Atlanta, GA (March 26, 1997)." The undersigned has recently obtained a copy of this alleged document and provides a copy for the Office herewith in connection with a concurrently filed supplemental information disclosure statement.

Double Patenting

Claims 31-54 stand rejected for obviousness-type double patenting over the claims of U.S. Patents 6,315,720, 6,561,977, 6,755,784, 6,869,399, and 7,141,018. Enclosed with the present paper is a terminal disclaimer over these patents, thereby obviating the obviousness-type double patenting rejection.

Claims 31-54 stand provisionally rejected under 35 U.S.C. § 103(a) as obvious over co-pending and commonly assigned Application No. 11/104,013. Applicants request that this provisional rejection be held in abeyance until the claims of the current application are found allowable.

35 U.S.C. § 101

Claims 35-41 stand rejected under 35 U.S.C. § 101 as allegedly claiming an invention that does not transform any subject matter and that has no tie to any machine, article of

manufacture or a composition of matter. The Action alleges that the independent claims[1] are directed to male/female patients, but the body of the claims fail to recite steps towards treating the patients. Applicants traverse this rejection.

Independent claims 31, 32, 39, 46, and 49 have been amended to recite the claimed methods include a step of administering thalidomide to the patient, which thereby recites a step towards treating a patient. Applicants submit that the claims recite 35 U.S.C. § 101 patentable subject matter and request that the rejection be withdrawn.

35 U.S.C. § 112

Claims 31-54 stand rejected under 35 U.S.C. § 112, second paragraph, for alleged indefiniteness. In particular, claims 31, 32, 39, 46, and 49 are allegedly indefinite because the claims do not recite a step towards treating a patient. The Action also alleges that the term "permitting…" is not a method step and that no steps have been recited in the body of the claims regarding treatment of the patient.

Applicants traverse this rejection. Claims 31, 32, 39, 46, and 49 have been amended to recite the claimed methods include a step of administering thalidomide to the patient, and therefore obviates the rejection with respect to an alleged lack of a step towards treating a patient. Moreover, Applicants submit that one skilled in the art would understand the claims to be definite with respect to treating a patient with thalidomide wherein said treatment is permitted only after certain steps are completed and a prescription approval code generated, as provided in the claims. It is clear that the claims encompass a method of controlling a patient's access to certain drugs, namely thalidomide, and that only after certain criteria have been satisfied is a patient permitted to receive the drug. Applicants respectfully request reconsideration and withdraw of this rejection.

35 U.S.C. § 102

Claims 31-54 stand rejected under 35 U.S.C. § 102(a) as being allegedly anticipated by Transcript, Thalidomide: Potential Benefits and Risks, an open public scientific workshop, Sponsored by National Institutes of Health, Food, and Drug Administration, Centers for

[1] The Action at page 5 states that claims 15, 22, 29, and 34 are independent. Those numbered claims are currently pending as independent claims in co-pending application no. 11/104,013. The independent claims of the current application relating to the treatment of male/female patients include claims 31, 32, 39, 46, and 49.

Disease Control and Prevention, September 9, 1997 (hereinafter, "Transcript"). Applicants traverse this rejection.

For a rejection under 35 U.S.C. §102(a) to be properly founded, the cited reference must teach, either expressly or inherently, each and every element of the claimed invention. *See, e.g. Hybritech Inc. v. Monoclonal Antibodies, Inc*., 231 USPQ 81 (Fed. Cir. 1986). Since the Transcript does not teach each and every element of the claimed invention, it does not anticipate the claims.

There is at least one element of the claimed invention that is not taught, either expressly or inherently, by the Transcript. For example, each of independent claims 31, 32, 39, 46, and 49 recite that the claimed invention includes the retrieval of prescription approval code prior to permitting prescriptions for thalidomide to be filled by a pharmacy. The Transcript fails to teach, inter alia, at least this aspect of the claimed invention, and thus can not be said to anticipate the claims. For at least this reason, the anticipation rejection over the Transcript should be withdrawn.

Conclusion

The foregoing represents a *bona fide* attempt to advance the present case to allowance. Applicants submit that the claims are in condition for allowance and an early Notice of Allowance is respectfully requested.

If the Examiner believes that a telephone conference would expedite prosecution of this application, he is invited to call the undersigned counsel at the below telephone number.

Date: July 9, 2008

/Angela Verrecchio/
Angela Verrecchio
Registration No. 54,510

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2929 Arch Street, 12th Floor
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PTO/SB/26 (01-08)
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TERMINAL DISCLAIMER TO OBVIATE A DOUBLE PATENTING REJECTION OVER A "PRIOR" PATENT	Docket Number (Optional) CELG-0508

In re Application of: Bruce A. Williams and Joseph K. Kaminski

Application No.: 11/437,551

Filed: May 19, 2006

For: Methods For Delivering A Drug To A Patient While Restricting Access To The Drug By Patients For Whom The Drug May Be Contraindicated

The owner*, Celgene Corporation, of 100 percent interest in the instant application hereby disclaims, except as provided below, the terminal part of the statutory term of any patent granted on the instant application which would extend beyond the expiration date of the full statutory term **prior patent** No. 6315720, 6561977 as the term of said prior patent is defined in 35 U.S.C. 154 and 173, and as the term of said **prior patent** is presently shortened by any terminal disclaimer. The owner hereby agrees that any patent so granted on the instant application shall be enforceable only for and during such period that it and the **prior patent** are commonly owned. This agreement runs with any patent granted on the instant application and is binding upon the grantee, its successors or assigns.

In making the above disclaimer, the owner does not disclaim the terminal part of the term of any patent granted on the instant application that would extend to the expiration date of the full statutory term as defined in 35 U.S.C. 154 and 173 of the **prior patent**, "as the term of said **prior patent** is presently shortened by any terminal disclaimer," in the event that said **prior patent** later:

expires for failure to pay a maintenance fee;
is held unenforceable;
is found invalid by a court of competent jurisdiction;
is statutorily disclaimed in whole or terminally disclaimed under 37 CFR 1.321;
has all claims canceled by a reexamination certificate;
is reissued; or
is in any manner terminated prior to the expiration of its full statutory term as presently shortened by any terminal disclaimer.

Check either box 1 or 2 below, if appropriate.

1. ☐ For submissions on behalf of a business/organization (e.g., corporation, partnership, university, government agency, etc.), the undersigned is empowered to act on behalf of the business/organization.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

2. ☑ The undersigned is an attorney or agent of record. Reg. No. 54,510

/Angela Verrecchio/ — Signature
July 9, 2008 — Date

Angela Verrecchio — Typed or printed name

(215) 568-3100 — Telephone Number

☑ Terminal disclaimer fee under 37 CFR 1.20(d) included.

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*Statement under 37 CFR 3.73(b) is required if terminal disclaimer is signed by the assignee (owner).
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expires for failure to pay a maintenance fee;
is held unenforceable;
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2. ☑ The undersigned is an attorney or agent of record. Reg. No. 54,510

/Angela Verrecchio/ — Signature

July 9, 2008 — Date

Angela Verrecchio — Typed or printed name

(215) 568-3100 — Telephone Number

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Application No.: 11/437,551

Filed: May 19, 2006

For: Methods For Delivering A Drug To A Patient While Restricting Access To The Drug By Patients For Whom The Drug May Be Contraindicated

The owner*, Celgene Corporation, of 100 percent interest in the instant application hereby disclaims, except as provided below, the terminal part of the statutory term of any patent granted on the instant application which would extend beyond the expiration date of the full statutory term **prior patent** No. 7141018 as the term of said prior patent is defined in 35 U.S.C. 154 and 173, and as the term of said **prior patent** is presently shortened by any terminal disclaimer. The owner hereby agrees that any patent so granted on the instant application shall be enforceable only for and during such period that it and the **prior patent** are commonly owned. This agreement runs with any patent granted on the instant application and is binding upon the grantee, its successors or assigns.

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2. ☑ The undersigned is an attorney or agent of record. Reg. No. 54,510

/Angela Verrecchio/ — Signature
July 9, 2008 — Date

Angela Verrecchio — Typed or printed name

(215) 568-3100 — Telephone Number

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Doc code :IDS
Doc description: Information Disclosure Statement (IDS) Filed

PTO/SB/08a (03-08)
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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	11437551
Filing Date	2006-05-19
First Named Inventor	Bruce A. Williams
Art Unit	3736
Examiner Name	Michael Astorino
Attorney Docket Number	CELG-0508

U.S.PATENTS

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
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	1							☐

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Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	11437551
	Filing Date	2006-05-19
	First Named Inventor	Bruce A. Williams
	Art Unit	3736
	Examiner Name	Michael Astorino
	Attorney Docket Number	CELG-0508

	1	"Preventing Birth Defects Due To Thalidomide Exposure", Sheraton Colony Square Hotel, March 26, 1997, 27 pages	☐
	2	Pregnancy Prevention Program for Women on Accutane isotretinoin. Accutane Therapy for Women of Childbearing Potential. Physicians' and Healthcare Professionals' Guide. Roche. 1994	☐
	3	Guide to the CLOZARIL Patient Monitoring Service. A reference manual for the CLOZARIL PATIENT MONITORING SERVICE. First Edition (November 1997), 45 pages	☐

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EXAMINER SIGNATURE

Examiner Signature		Date Considered	

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[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**		
	Application Number	11437551
	Filing Date	2006-05-19
	First Named Inventor	Bruce A. Williams
	Art Unit	3736
	Examiner Name	Michael Astorino
	Attorney Docket Number	CELG-0508

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

☐ See attached certification statement.

☒ Fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☐ None

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Angela Verrecchio/	Date (YYYY-MM-DD)	2008-07-09
Name/Print	Angela Verrecchio	Registration Number	54,510

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Electronic Patent Application Fee Transmittal

Application Number:	11437551
Filing Date:	19-May-2006
Title of Invention:	Methods for delivering a drug to a patient while restricting access to the drug by patients for whom the drug may be contraindicated
First Named Inventor/Applicant Name:	Bruce A. Williams
Filer:	Angela Verrecchio/Kelly Freels
Attorney Docket Number:	CELG-0508

Filed as Large Entity

Utility Filing Fees

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Miscellaneous:				
Submission- Information Disclosure Stmt	1806	1	180	180
Processing Fee, except for Provis. apps	1808	1	130	130
		Total in USD ($)		**310**

Electronic Acknowledgement Receipt

EFS ID:	3589217
Application Number:	11437551
International Application Number:	
Confirmation Number:	3533
Title of Invention:	Methods for delivering a drug to a patient while restricting access to the drug by patients for whom the drug may be contraindicated
First Named Inventor/Applicant Name:	Bruce A. Williams
Customer Number:	23377
Filer:	Angela Verrecchio/Kelly Freels
Filer Authorized By:	Angela Verrecchio
Attorney Docket Number:	CELG-0508
Receipt Date:	09-JUL-2008
Filing Date:	19-MAY-2006
Time Stamp:	15:46:51
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Deposit Account
Payment was successfully received in RAM	$310
RAM confirmation Number	963
Deposit Account	233050
Authorized User	

The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:

Charge any Additional Fees required under 37 C.F.R. Section 1.16 (National application filing, search, and examination fees)

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Charge any Additional Fees required under 37 C.F.R. Section 1.20 (Post Issuance fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.21 (Miscellaneous fees and charges)

File Listing:

Document Number	Document Description	File Name	File Size(Bytes) /Message Digest	Multi Part /.zip	Pages (if appl.)
1	Miscellaneous Incoming Letter	Transmittal.PDF	239839 b0ef9754bc28d7fc5c3ec5902297a57798d0b481	no	1
Warnings:					
Information:					
2		ReplytoNonFinaltoOA50108.PDF	154521 c6f13e49cc20201de857f0c3185b9594ca847a4d	yes	13
	Multipart Description/PDF files in .zip description				
	Document Description		**Start**	**End**	
	Amendment - After Non-Final Rejection		1	1	
	Specification		2	2	
	Claims		3	10	
	Applicant Arguments/Remarks Made in an Amendment		11	13	
Warnings:					
Information:					
3	Terminal Disclaimer Filed	TerminalDisclaimer1.PDF	134213 bd15d950b6d96ec081e02cd85e8fcf3f983a3470	no	1
Warnings:					
Information:					
4	Terminal Disclaimer Filed	TerminalDisclaimer2.PDF	131198 28e36a1b191fb32a835c3b3b81825a1ff7007ec2	no	1
Warnings:					
Information:					
5	Terminal Disclaimer Filed	TerminalDisclaimer3.PDF	131157 1ff96a87b870a215c64c9a705aa201e2c975b917	no	1
Warnings:					
Information:					

6	NPL Documents	Guide_Clozaril_Nov1997_45 pgs.PDF	1869358 b722f5514186ce8b2deee1c71674d0e6edc168f4	no	45

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Information:

7	NPL Documents	PregPreventProgAccutane_ Roche_1994.PDF	896233 653af87b849007d366be9c88ca9ffef3bb4fb60e	no	15

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8	NPL Documents	PreventBirthDefectsThalmid Expos_32697.PDF	1485234 b9e2bf5763ddf19706d3df58ef3394c1ae1bf3b8	no	30

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Information:

9	Information Disclosure Statement (IDS) Filed	IDS070908.PDF	30381 3e8e2699a045571871708aa9256be90b1ad677bf	no	4

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10	Fee Worksheet (PTO-06)	fee-info.pdf	8378 9f2a924b5e79f7ee288f56d6cf8008b87e7f830a	no	2

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Total Files Size (in bytes):	5080512

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New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

PTO/SB/21 (01-08)
Approved for use through 07/31/2008. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Total Number of Pages in This Submission	111

Application Number	11/437,551
Filing Date	May 19, 2006
First Named Inventor	Bruce A. Williams
Art Unit	3736
Examiner Name	Michael Astorino
Attorney Docket Number	CELG-0508

ENCLOSURES *(Check all that apply)*

- ☐ Fee Transmittal Form
  - ☐ Fee Attached
- ☑ Amendment/Reply
  - ☐ After Final
  - ☐ Affidavits/declaration(s)
- ☐ Extension of Time Request
- ☐ Express Abandonment Request
- ☑ Information Disclosure Statement
- ☐ Certified Copy of Priority Document(s)
- ☐ Reply to Missing Parts/ Incomplete Application
  - ☐ Reply to Missing Parts under 37 CFR 1.52 or 1.53
- ☐ Drawing(s)
- ☐ Licensing-related Papers
- ☐ Petition
- ☐ Petition to Convert to a Provisional Application
- ☐ Power of Attorney, Revocation
- ☐ Change of Correspondence Address
- ☑ Terminal Disclaimer
- ☐ Request for Refund
- ☐ CD, Number of CD(s) _____
  - ☐ Landscape Table on CD
- ☐ After Allowance Communication to TC
- ☐ Appeal Communication to Board of Appeals and Interferences
- ☐ Appeal Communication to TC **(Appeal Notice, Brief, Reply Brief)**
- ☐ Proprietary Information
- ☐ Status Letter
- ☑ Other Enclosure(s) (please Identify below):

3 References listed on Information Disclosure Statement

Remarks

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm Name	WOODCOCK WASHBURN, LLP		
Signature	/Angela Verrecchio/		
Printed name	Angela Verrecchio		
Date	July 9, 2008	Reg. No.	54,510

CERTIFICATE OF TRANSMISSION/MAILING

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Signature			
Typed or printed name		Date	

Document code: WFEE

United States Patent and Trademark Office
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PTO/SB/06 (07-06)
Approved for use through 1/31/2007. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

PATENT APPLICATION FEE DETERMINATION RECORD

Substitute for Form PTO-875

Application or Docket Number	Filing Date	☐ To be Mailed
11/437,551	05/19/2006	

APPLICATION AS FILED – PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA	SMALL ENTITY RATE ($)	SMALL ENTITY FEE ($)	OR	OTHER THAN SMALL ENTITY RATE ($)	OTHER THAN SMALL ENTITY FEE ($)
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A			N/A	
☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A			N/A	
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A			N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*	X $ =		OR	X $ =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*	X $ =			X $ =	
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $250 ($125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).						
☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))							
			TOTAL			TOTAL	

* If the difference in column 1 is less than zero, enter "0" in column 2.

APPLICATION AS AMENDED – PART II

AMENDMENT 07/09/2008

	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	SMALL ENTITY RATE ($)	SMALL ENTITY ADDITIONAL FEE ($)	OR	OTHER THAN SMALL ENTITY RATE ($)	OTHER THAN SMALL ENTITY ADDITIONAL FEE ($)
Total (37 CFR 1.16(i))	* 24	Minus	** 24	= 0	X $ =		OR	X $50=	0
Independent (37 CFR 1.16(h))	* 5	Minus	***5	= 0	X $ =		OR	X $210=	0
☐ Application Size Fee (37 CFR 1.16(s))									
☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
					TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	0

AMENDMENT

	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	SMALL ENTITY RATE ($)	SMALL ENTITY ADDITIONAL FEE ($)	OR	OTHER THAN SMALL ENTITY RATE ($)	OTHER THAN SMALL ENTITY ADDITIONAL FEE ($)
Total (37 CFR 1.16(i))	*	Minus	**	=	X $ =		OR	X $ =	
Independent (37 CFR 1.16(h))	*	Minus	***	=	X $ =		OR	X $ =	
☐ Application Size Fee (37 CFR 1.16(s))									
☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
					TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.

** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".

*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".

The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.

Legal Instrument Examiner:
/EVELYN G. NIMMONS/

Application Number	Application/Control No.	Applicant(s)/Patent under Reexamination	
	11/437,551	WILLIAMS ET AL.	

Document Code - DISQ	Internal Document – DO NOT MAIL

TERMINAL DISCLAIMER	☒ APPROVED	☐ DISAPPROVED
Date Filed : 7/9/08	This patent is subject to a Terminal Disclaimer	

Approved/Disapproved by:
ANDRE ROBINSON

Application Number	Application/Control No.	Applicant(s)/Patent under Reexamination	
	11/437,551	WILLIAMS ET AL.	

Document Code - DISQ	Internal Document – DO NOT MAIL

TERMINAL DISCLAIMER	☒ APPROVED	☐ DISAPPROVED
Date Filed : 7/9/08	This patent is subject to a Terminal Disclaimer	

Approved/Disapproved by:
ANDRE ROBINSON

Application Number	Application/Control No.	Applicant(s)/Patent under Reexamination
	11/437,551	WILLIAMS ET AL.

Document Code - DISQ	Internal Document – DO NOT MAIL

TERMINAL DISCLAIMER	☒ APPROVED	☐ DISAPPROVED
Date Filed : 7/9/08	This patent is subject to a Terminal Disclaimer	

Approved/Disapproved by:
ANDRE ROBINSON

DOCKET NO.: CELG-0508 **PATENT**
Application No.: 11/437,551
Office Action Dated: May 1, 2008

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:
Bruce A. Williams and Joseph K. Kaminski

Confirmation No.: **3533**

Application No.: **11/437,551**

Group Art Unit: **3736**

Filing Date: **May 19, 2006**

Examiner: **Michael Astorino**

For: **Methods For Delivering A Drug To A Patient While Restricting Access To The Drug By Patients For Whom The Drug May Be Contraindicated**

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

SUPPLEMENTAL REPLY PURSUANT TO 37 CFR § 1.111

In response to the Official Action dated **May 1, 2008**, reconsideration is respectfully requested in view of the supplemental amendments and/or remarks as indicated below:

☒ **Amendments to the Specification** begin on page 2 of this paper.

☒ **Amendments to the Claims** are reflected in the listing of the claims which begins on page 3 of this paper.

☐ **Amendments to the Drawings** begin on page of this paper and include an attached replacement sheet.

☒ **Remarks** begin on page 11 of this paper.

Amendments to Specification

On page 1, please delete the paragraph immediately after "CROSS REFERENCE TO RELATED APPLICATIONS" and replace with the following:

This application is a continuation of U.S. Application Serial No. 11/028,144, filed January 3, 2005, now U.S. Patent 7,141,018, which is a continuation of U.S. Application Serial No. 10/762,880, filed January 22, 2004, now U.S. Patent No. 6,869,399, which is a continuation of U.S. Application Serial No. 10/383,275, filed March 7, 2003, now U.S. Pat. No. 6,755,784, which is a continuation of U.S. Application Serial No. 09/965,155, filed September 27, 2001, now U.S. Pat. No. 6,561,977, which is a continuation of U.S. Application No. 09/694,217, filed October 23, 2000, now U.S. Pat. No. 6,315,720, the entirety of each of which is hereby incorporated by reference.

This listing of claims will replace all prior versions, and listings, of claims in the application.

Listing of Claims:

Claims 1-31 (Canceled).

32. (Currently Amended) A method of treating a male patient, suffering from erythema nodosum leprosum, with thalidomide, said method comprising permitting prescriptions for thalidomide to be filled by a pharmacy only after the pharmacy has retrieved an approval code for the prescription, wherein the generation of the prescription approval code comprises the following steps:

(a) registering a prescriber and the pharmacy with a distributor of thalidomide;

(b) determining whether the patient is able to understand and reliably carry out instructions;

(c) upon determination that the patient is able to carry out the instructions, providing oral and written warnings of the hazard of taking thalidomide and exposing fetus to the drug;

(d) further providing oral and written warnings of the risk of possible contraception failure and of the need to use barrier contraception when having sexual intercourse with women of child bearing potential;

(e) obtaining acknowledgement of said warnings from the patient;

(f) registering the patient with the distributor; ~~and~~

(g) upon obtaining the acknowledgement and registration, generating the prescription approval code to be retrieved by the pharmacy before the prescription is filled; and

(h) administering thalidomide to the patient.

33. (Previously Presented) The method of claim 32, wherein the acknowledgement requires the patient's acknowledgement of one or more of the following:

(a) the understanding that thalidomide must not be taken if unprotected sex cannot be avoided;

(b) the understanding of potential birth defects;

(c) that the patient has been advised of the need for barrier contraception by the prescriber;

(d) the obligation to inform the prescriber if the patient's sexual partner is suspected of becoming or being pregnant;

(e) that thalidomide is solely for the use of the patient himself and must not be shared with any other person;

(f) that the patient has read the information brochure or viewed the information film on thalidomide;

(g) that the semen or blood must not be donated during the thalidomide treatment;

(h) that all of the patient's inquiries regarding thalidomide treatment have been answered by the prescribing physician; or

(i) the patient's understanding that participation in a survey and patient registry is required during the thalidomide treatment.

34. (Previously Presented) The method of claim 32 further comprising providing the patient, prior to generation of the approval code, with warnings of the side effects associated with administration of thalidomide, wherein said side effects are non-teratogenic side effects.

35. (Previously Presented) The method of claim 32 further comprising obtaining a written authorization by the prescriber prior to generation of the approval code.

36. (Previously Presented) The method of claim 32, wherein the prescription approval code is retrieved from a computer readable storage medium.

37. (Previously Presented) The method of claim 32, wherein the acknowledgement is a written informed consent.

38. (Previously Presented) The method of claim 37, wherein the written informed consent is registered in the medium prior to generation of the prescription approval code.

39. (Currently Amended) A method of treating a female patient, suffering from erythema nodosum leprosum, with thalidomide, said method comprising permitting prescriptions for thalidomide to be filled by a pharmacy only after the pharmacy has retrieved an approval code for the prescription, wherein the generation of the prescription approval code comprises the following steps:

(a) registering a prescriber and the pharmacy with a distributor of thalidomide;

(b) determining whether the patient is able to understand and reliably carry out instructions;

(c) upon determination that the patient is able to carry out the instructions, determining whether the patient is of child bearing potential;

(d) upon determining that the patient is of child bearing potential, providing oral and written warnings of the hazard of taking thalidomide and exposing fetus to the drug;

(e) further providing oral and written warnings of the risk of possible contraception failure and of the need to simultaneous use of two reliable forms of contraception;

(f) obtaining acknowledge of said warnings from the patient;

(g) determining, prior to the scheduled beginning of the thalidomide therapy, whether the patient is pregnant;

(h) registering the patient with the distributor; ~~and~~

(i) generating the prescription approval code to be retrieved by the pharmacy before the prescription is filled; and

(j) administering thalidomide to the patient.

40. (Previously Presented) The method of claim 39, wherein the acknowledgement requires the patient's acknowledgement of one or more of the following:

(a) the understanding that thalidomide must not be taken if the patient is pregnant, breastfeeding a baby, or able to get pregnant and not using birth controls;

(b) the understanding of potential birth defects;

(c) the warning received by the prescriber regarding said birth defects;

(d) the understanding of the need for at least two forms of contraception prior to, during, and subsequent to thalidomide treatment;

(e) the obligation to undergo a pregnancy test prior to starting thalidomide treatment;

(f) the obligation to undergo a pregnancy test during the thalidomide treatment;

(g) the obligation to discontinue thalidomide treatment and inform theprescriber in the case that the patient is suspected of becoming or being pregnant;

(h) that the patient is not currently pregnant and will not try to become pregnant for at least 4 weeks after the completion of thalidomide treatment;

(i) that thalidomide is solely for the use of the patient herself and must not be shared with any other person;

(j) that the patient has read the information brochure or viewed the information film on thalidomide;

(k) that the blood must not be donated during the thalidomide treatment;

(l) that all of the patient's inquiries regarding thalidomide treatment have been answered by the prescriber; or

(m) the patient's understanding that participation in a survey and patient registry is required during the thalidomide treatment.

41. (Previously Presented) The method of claim 39 further comprising providing the patient, prior to generation of the approval code, with warnings of the side effects associated with administration of thalidomide, wherein said side effects are non-teratogenic side effects.

42. (Previously Presented) The method of claim 39 further comprising obtaining a written authorization by the prescriber prior to generation of the approval code.

43. (Previously Presented) The method of claim 39, wherein the prescription approval code is retrieved from a computer readable storage medium.

44. (Previously Presented) The method of claim 39, wherein the acknowledgement is a written informed consent.

45. (Previously Presented) The method of claim 44, wherein the informed written consent is registered in the medium prior to generation of the prescription approval code.

46. (Currently Amended) A method of treating a male patient, suffering from erythema nodosum leprosum, with thalidomide, said method comprising permitting prescriptions for thalidomide to be filled by a pharmacy only after the pharmacy has retrieved an approval code for the prescription from a computer readable storage medium, wherein the generation of the prescription approval code comprises the following steps:

(A) registering a prescriber and the pharmacy in the computer readable storage medium;

(B) determining whether the patient is able to understand and reliably carry out instructions;

(C) upon determination that the patient is able to carry out instructions, providing oral and written warnings of the hazard of taking thalidomide and exposing fetus to the drug;

(D) further providing oral and written warnings of the risk of possible contraception failure and of the need to use barrier contraception when having sexual intercourse with women of child bearing potential;

(E) obtaining informed consent from the patient;

(F) registering the patient in the computer readable storage medium; ~~and~~

(G) upon obtaining the informed consent and registration, generating the prescription approval code to be retrieved by the pharmacy before the prescription is filled, wherein said informed consent requires the patient's acknowledgement of one or more of the following:

(a) the understanding that thalidomide must not be taken if unprotected sex cannot be avoided;

(b) the understanding of potential birth defects;

(c) that the patient has been advised of the need for barrier contraception by the prescriber;

(d) the obligation to inform the prescriber if the patient's sexual partner is suspected of becoming or being pregnant;

(e) that thalidomide is solely for the use of the patient himself and must not be shared with any other person;

(f) that the patient has read the information brochure or viewed the information film on thalidomide;

(g) that the semen or blood must not be donated during the thalidomide treatment;

(h) that all of the patient's inquiries regarding thalidomide treatment have been answered by the prescribing physician; or

(i) the patient's understanding that participation in a survey and patient registry is required during the thalidomide treatment; and

(H) administering thalidomide to the patient.

47. (Previously Presented) The method of claim 46 further comprising providing the patient, prior to generation of the approval code, with warnings of the side effects associated with administration of thalidomide, wherein said side effects are non-teratogenic side effects.

48. (Previously Presented) The method of claim 46 further comprising obtaining a written authorization by the prescriber prior to generation of the approval code.

49. (Currently Amended) A method of treating a female patient, suffering from erythema nodosum leprosum, with thalidomide, said method comprising permitting prescriptions for thalidomide to be filled by a pharmacy only after the pharmacy has retrieved an approval code for the prescription from a computer readable storage medium, wherein the generation of the prescription approval code comprises the following steps:

(A) registering a prescriber and the pharmacy in the computer readable storage medium;

(B) determining whether the patient is able to understand and reliably carry out instructions;

(C) upon determination that the patient is able to carry out instructions, determining whether the patient is of child bearing potential;

(D) upon determining that the patient is of child bearing potential, providing oral and written warnings of the hazard of taking thalidomide and exposing fetus to the drug;

(E) further providing oral and written warnings of the risk of possible contraception failure and of the need to simultaneous use of two reliable forms of contraception;

(F) obtaining informed consent from the patient;

(G) determining, prior to the scheduled beginning of the thalidomide therapy, whether the patient is pregnant;

(H) registering the patient in the computer readable storage medium; ~~and~~

(I) generating the prescription approval code to be retrieved by the pharmacy before the prescription is filled; and

(J) administering thalidomide to the patient,

wherein said informed consent requires the patient's acknowledgement of one or more of the following:

(a) the understanding that thalidomide must not be taken if the patient is pregnant, breastfeeding a baby, or able to get pregnant and not using birth controls;

(b) the understanding of potential birth defects;

(c) the warning received by the prescriber regarding said birth defects;

(d) the understanding of the need for at least two forms of contraception prior to, during, and subsequent to thalidomide treatment;

(e) the obligation to undergo a pregnancy test prior to starting thalidomide treatment;

(f) the obligation to undergo a pregnancy test during the thalidomide treatment;

(g) the obligation to discontinue thalidomide treatment and inform the prescriber in the case that the patient is suspected of becoming or being pregnant;

(h) that the patient is not currently pregnant and will not try to become pregnant for at least 4 weeks after the completion of thalidomide treatment;

(i) that thalidomide is solely for the use of the patient herself and must not be shared with any other person;

(j) that the patient has read the information brochure or viewed the information film on thalidomide;

(k) that the blood must not be donated during the thalidomide treatment,

(l) that all of the patient's inquiries regarding thalidomide treatment have been answered by the prescriber; or

(m) the patient's understanding that participation in a survey and patient registry is required during the thalidomide treatment.

50. (Previously Presented) The method of claim 49 further comprising providing the patient, prior to generation of the approval code, with warnings of the side effects associated with administration of thalidomide, wherein said side effects are non-teratogenic side effects.

51. (Previously Presented) The method of claim 49 further comprising obtaining a written authorization by the prescriber prior to generation of the approval code.

52. (Previously Presented) The method of claim 49 wherein the patient is required to use contraception for at least 4 weeks prior to generation of the approval code.

53. (Previously Presented) The method of claim 49 wherein the patient is required to use contraception during thalidomide therapy.

54. (Previously Presented) The method of claim 49 wherein the patient is required to use contraception for at least 4 weeks after discontinuation of thalidomide treatment.

REMARKS

Applicants are filing this supplemental response to the official action dated May 1, 2008. Claim 31 is now canceled, and claims 32-54 are currently pending. Claims 32, 39, 46, and 49 are shown as "currently amended" pursuant to Applicants' previously filed response to the official action, filed on July 9, 2008. Since it is Applicants' understanding that those amendments have not yet been entered, their status is designated as "currently amended."

Conclusion

The foregoing represents a *bona fide* attempt to advance the present case to allowance. Applicants submit that the claims are in condition for allowance and an early Notice of Allowance is respectfully requested.

If the Examiner believes that a telephone conference would expedite prosecution of this application, he is invited to call the undersigned counsel at the below telephone number.

Date: October 14, 2008

/Angela Verrecchio/
Angela Verrecchio
Registration No. 54,510

Woodcock Washburn LLP
Cira Centre
2929 Arch Street, 12th Floor
Philadelphia, PA 19104-2891
Telephone: (215) 568-3100
Facsimile: (215) 568-3439

Electronic Acknowledgement Receipt

EFS ID:	4109534
Application Number:	11437551
International Application Number:	
Confirmation Number:	3533
Title of Invention:	Methods for delivering a drug to a patient while restricting access to the drug by patients for whom the drug may be contraindicated
First Named Inventor/Applicant Name:	Bruce A. Williams
Customer Number:	23377
Filer:	Angela Verrecchio/Kelly Freels
Filer Authorized By:	Angela Verrecchio
Attorney Docket Number:	CELG-0508
Receipt Date:	14-OCT-2008
Filing Date:	19-MAY-2006
Time Stamp:	14:57:29
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Miscellaneous Incoming Letter	Transmittal.PDF	1752347 4025f73da2ca6fffcaa7423e8912b7be5c6ec869	no	1

Warnings:

Information:

2		Response.PDF	108798 bffab1483f32a33d3c580de6fd761aae1429d709	yes	11

Multipart Description/PDF files in .zip description

Document Description	Start	End
Amendment/Req. Reconsideration-After Non-Final Reject	1	1
Specification	2	2
Claims	3	10
Applicant Arguments/Remarks Made in an Amendment	11	11

Warnings:

Information:

Total Files Size (in bytes):	1861145

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111
If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371
If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office
If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

PTO/SB/21 (09-08)
Approved for use through 10/31/2008. OMB 0651-0031
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TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Total Number of Pages in This Submission	12

Application Number	11/437,551
Filing Date	May 19, 2006
First Named Inventor	Bruce A. Williams
Art Unit	3736
Examiner Name	Michael C. Astorino
Attorney Docket Number	CELG-0508

ENCLOSURES *(Check all that apply)*

- ☐ Fee Transmittal Form
  - ☐ Fee Attached
- ☑ Amendment/Reply
  - ☐ After Final
  - ☐ Affidavits/declaration(s)
- ☐ Extension of Time Request
- ☐ Express Abandonment Request
- ☐ Information Disclosure Statement
- ☐ Certified Copy of Priority Document(s)
- ☐ Reply to Missing Parts/ Incomplete Application
  - ☐ Reply to Missing Parts under 37 CFR 1.52 or 1.53
- ☐ Drawing(s)
- ☐ Licensing-related Papers
- ☐ Petition
- ☐ Petition to Convert to a Provisional Application
- ☐ Power of Attorney, Revocation
- ☐ Change of Correspondence Address
- ☐ Terminal Disclaimer
- ☐ Request for Refund
- ☐ CD, Number of CD(s) _____
  - ☐ Landscape Table on CD
- ☐ After Allowance Communication to TC
- ☐ Appeal Communication to Board of Appeals and Interferences
- ☐ Appeal Communication to TC **(Appeal Notice, Brief, Reply Brief)**
- ☐ Proprietary Information
- ☐ Status Letter
- ☐ Other Enclosure(s) (please Identify below):

Remarks

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm Name	Woodcock Washburn, LLP		
Signature	/Angela Verrecchio/		
Printed name	Angela Verrecchio		
Date	October 14, 2008	Reg. No.	54,510

CERTIFICATE OF TRANSMISSION/MAILING

I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below:

Signature			
Typed or printed name		Date	

PTO/SB/06 (07-06)
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Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

PATENT APPLICATION FEE DETERMINATION RECORD

Substitute for Form PTO-875

Application or Docket Number	Filing Date	☐ To be Mailed
11/437,551	05/19/2006	

APPLICATION AS FILED – PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA	SMALL ENTITY RATE ($)	SMALL ENTITY FEE ($)	OR	OTHER THAN SMALL ENTITY RATE ($)	OTHER THAN SMALL ENTITY FEE ($)
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A			N/A	
☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A			N/A	
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A			N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*	X $ =		OR	X $ =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*	X $ =			X $ =	
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $250 ($125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).						
☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))							
			TOTAL			TOTAL	

* If the difference in column 1 is less than zero, enter "0" in column 2.

APPLICATION AS AMENDED – PART II

AMENDMENT	10/14/2008	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	SMALL ENTITY RATE ($)	SMALL ENTITY ADDITIONAL FEE ($)	OR	OTHER THAN SMALL ENTITY RATE ($)	OTHER THAN SMALL ENTITY ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	* 23	Minus	** 24	= 0	X $ =		OR	X $52=	0
	Independent (37 CFR 1.16(h))	* 5	Minus	***5	= 0	X $ =		OR	X $220=	0
	☐ Application Size Fee (37 CFR 1.16(s))									
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
						TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	0

AMENDMENT		(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	RATE ($)	ADDITIONAL FEE ($)		RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	*	Minus	**	=	X $ =		OR	X $ =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=	X $ =		OR	X $ =	
	☐ Application Size Fee (37 CFR 1.16(s))									
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
						TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.

** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".

*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".

The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.

Legal Instrument Examiner:
/Kimberly Cooper/

This collection of information is required by 37 CFR 1.16. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/437,551	05/19/2006	Bruce A. Williams	CELG-0508	3533

23377 7590 01/08/2009

WOODCOCK WASHBURN LLP
CIRA CENTRE, 12TH FLOOR
2929 ARCH STREET
PHILADELPHIA, PA 19104-2891

EXAMINER	
NAQI, SHARICK	

ART UNIT	PAPER NUMBER
3769	

MAIL DATE	DELIVERY MODE
01/08/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	11/437,551	WILLIAMS ET AL.	
	Examiner	Art Unit	
	SHARICK NAQI	3769	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10/14/2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *32-54* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *32-54* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7/9/2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Examiner acknowledges the response filed on October 14, 2008.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 32-54 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. In particular, claims 32-54 are drawn to a process. Under 35 U.S.C. §101 a process must 1) be tied to another statutory class (such as a particular apparatus) or 2) transform underlying subject matter (such as an article or materials) to a different state or thing. The claimed process steps do not transform underlying subject matter. Thus, to qualify as a 35 U.S.C. § 101 statutory process, the claims should positively recite the other statutory class (apparatus or thing) to which it is tied, for example by identifying the apparatus that accomplishes the method steps. The step of “administering thalidomide to the patient” does not constitute a sufficient tie to another statutory class because although an explicit definition of "administer" is not provided in the specification, a dictionary definition of the term is “to supervise the taking of” (http://www.thefreedictionary.com/administer). It is further noted that this step does not result in a transformation. Additionally a computer readable medium is not considered a sufficient tie in this case because the process appears to do nothing more than pull the data from the medium but does not require the medium to have a specific computer executable medium thereon to generate the codes. The

medium appears to simply be data storage so the mention of the medium in the claims is nothing more than an ancillary feature. The consent/authorization steps also do not provide a tie because the consent is not claimed on a tangible medium.

http://www.uspto.gov/web/offices/pac/dapp/opla/preognotice/section_101_05_15_2008.pdf

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim(s) 32-54 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Independent claims 32, 39, 46 and 49 state that "generation of an approval code *comprises the following steps*: . . . administering thalidomide to the patient." It is unclear to the Examiner how a step of administering thalidomide to the patient is generating a prescription approval code.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 32-54 are rejected under 35 U.S.C. 102(a) as being anticipated by Transcript, Thalidomide: Potential Benefits and Risks, an open public scientific workshop, Sponsored by National Institutes of Health, Food and Drug Administration, Centers for Disease Control and Prevention, September 9, 1997. (Hereinafter Transcript).

It is the Examiner's position that the reference teaches all the claimed limitations. As further support for this position, Examiner relies upon, as extrinsic evidence, Guide to CLOZARIL Patient Monitoring Service (provided in the Applicant's IDS and hereinafter Clozaril Guide) and Pregnancy Prevention Program for Women on Accutane (provided in the Applicant's IDS and hereinafter Accutane PPP), that were referenced by the transcript in the following passages:

> "Although we've received both positive and negative feedback about these suggestions on dispensing, the last two stimulated the most discussion, mainly pertaining to the idea that the pharmacist would also be a gatekeeper for thalidomide, and in some ways serve as the ultimate control over who receives the drug. This is not an idea without precedent. **For at least one drug, Clozaril, dispensing cannot be done unless the pharmacist is presented documentation of requisite laboratory results.**
>
> As an aside, it was encouraging to learn at the FDA meeting last Friday that Celgene will include the patient's diagnosis in their proposed registry, and would be able to monitor this data to limit inappropriate or trivial use of thalidomide.
>
> . . . the **Roche pregnancy program for women on Accutane, was a good starting point** . . ."

In the remarks filed July 9, 2008, applicant contested only that the reference failed to teach “retrieval of a prescription approval code prior to permitting prescriptions for thalidomide to be filled by a pharmacy”. However, the applicant failed to provide an explicit definition of an “approval code”. Transcript discloses that “dispensing cannot be done unless the pharmacist is presented documentation of requisite laboratory results” (Trancript page 141 of 149 paragraph 4). It is the Examiner’s position that the documentation of requisite laboratory results required by the pharmacist before dispensing medication is sufficient to meet the broadest reasonable interpretation of an "approval code".

Response to Arguments

Applicant's arguments filed July 9 2008 and October 14, 2008 have been fully considered but they are not persuasive. See rejections above for details.

The Applicant is invited to request an interview to discuss suggestions to overcome the applied prior art and/or any other rejection, requirement, etc. in the office action.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHARICK NAQI whose telephone number is (571)272-3041. The examiner can normally be reached on 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry M. Johnson III can be reached on 571-272-4768. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S. N./
Examiner, Art Unit 3769

/Michael C. Astorino/
Primary Examiner, Art Unit 3769

December 18, 2008

EAST Search History

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L1	3982	600/300.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2008/12/18 18:48
L2	5431	thalidomide and treatment	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2008/12/18 18:50
L3	1565	thalidomide same treatment	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2008/12/18 18:50
L4	191	thalidomide same treatment same prevention	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2008/12/18 18:50
L5	2	thalidomide same prescription same control	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2008/12/18 18:50
L6	0	thalidomide same prescription same prevention	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2008/12/18 18:52
L7	3	thalidomide same prescription same prevent$5	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2008/12/18 18:52

12/18/2008 6:53:36 PM
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Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	11437551	WILLIAMS ET AL.
	Examiner	Art Unit
	Michael Astorino	3736

SEARCHED

Class	Subclass	Date	Examiner
600	300-301	4/08	MA
128	920	4/08	MA
705	2-4	4/08	MA
235	375	4/08	MA

SEARCH NOTES

Search Notes	Date	Examiner
IDS	4/08	MA
See parent cases	4/08	MA
EAST Inventor Search	4/08	MA
STIC Search to Find sept 1997 Transcript	4/08	MA
Spoke with TQUAS(s) regarding 101 rejection	4/08	MA
West Search Timed out, lost class and text search	4/08	MA
STIC Search	December 2008	SN
Spoke with TQAS regarding 101 and 112 2nd rejections	December 2008	SN
EAST Text Search Updated	December 2008	SN

INTERFERENCE SEARCH

Class	Subclass	Date	Examiner

/S. N./ Examiner.Art Unit 3769	

Doc code :IDS
Doc description: Information Disclosure Statement (IDS) Filed

PTO/SB/08a (03-08)
Approved for use through 07/31/2008. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**		
	Application Number	11437551
	Filing Date	2006-05-19
	First Named Inventor	Bruce A. Williams
	Art Unit	3736
	Examiner Name	Michael Astorino
	Attorney Docket Number	CELG-0508

U.S.PATENTS						
Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
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ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /S.N./

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	1	"Preventing Birth Defects Due To Thalidomide Exposure", Sheraton Colony Square Hotel, March 26, 1997, 27 pages	☐
	2	Pregnancy Prevention Program for Women on Accutane isotretinoin. Accutane Therapy for Women of Childbearing Potential. Physicians' and Healthcare Professionals' Guide. Roche. 1994	☐
	3	Guide to the CLOZARIL Patient Monitoring Service. A reference manual for the CLOZARIL PATIENT MONITORING SERVICE. First Edition (November 1997), 45 pages	☐

If you wish to add additional non-patent literature document citation information please click the Add button

EXAMINER SIGNATURE

Examiner Signature	/Sharick Naqi/	Date Considered	12/18/2008

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/437,551	05/19/2006	Bruce A. Williams	CELG-0508	3533

23377 7590 02/25/2009

WOODCOCK WASHBURN LLP
CIRA CENTRE, 12TH FLOOR
2929 ARCH STREET
PHILADELPHIA, PA 19104-2891

EXAMINER	
NAQI, SHARICK	

ART UNIT	PAPER NUMBER
3769	

MAIL DATE	DELIVERY MODE
02/25/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Interview Summary	Application No.	Applicant(s)	
	11/437,551	WILLIAMS ET AL.	
	Examiner	Art Unit	
	SHARICK NAQI	3769	

All participants (applicant, applicant's representative, PTO personnel):

(1) *SHARICK NAQI*.

(2) *RICHARD GIRARDS*.

(3)*ANGELA VERRECCHIO*.

(4)*MICHAEL ASTORINO*.

Date of Interview: *23 February 2009*.

Type: a)☐ Telephonic b)☐ Video Conference
c)☒ Personal [copy given to: 1)☐ applicant 2)☒ applicant's representative]

Exhibit shown or demonstration conducted: d)☐ Yes e)☒ No.
If Yes, brief description: _____.

Claim(s) discussed: *Independent claims*.

Identification of prior art discussed: *N/A*.

Agreement with respect to the claims f)☐ was reached. g)☐ was not reached. h)☒ N/A.

Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: *Attorneys for applicants and Examiners discussed references of record, particularly in context of rejections under USC 102. Attorneys and Examiners also discussed potential claim amendments to overcome the rejections under USC 101 and 112*.

(A fuller description, if necessary, and a copy of the amendments which the examiner agreed would render the claims allowable, if available, must be attached. Also, where no copy of the amendments that would render the claims allowable is available, a summary thereof must be attached.)

THE FORMAL WRITTEN REPLY TO THE LAST OFFICE ACTION MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW. (See MPEP Section 713.04). If a reply to the last Office action has already been filed, APPLICANT IS GIVEN A NON-EXTENDABLE PERIOD OF THE LONGER OF ONE MONTH OR THIRTY DAYS FROM THIS INTERVIEW DATE, OR THE MAILING DATE OF THIS INTERVIEW SUMMARY FORM, WHICHEVER IS LATER, TO FILE A STATEMENT OF THE SUBSTANCE OF THE INTERVIEW. See Summary of Record of Interview requirements on reverse side or on attached sheet.

/Michael C. Astorino/ Primary Examiner, Art Unit 3769	571-272-4723

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11/437,551	05/19/2006	Bruce A. Williams	CELG-0508	3533

23377 7590 06/05/2009

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EXAMINER	
NAQI, SHARICK	

ART UNIT	PAPER NUMBER
3769	

MAIL DATE	DELIVERY MODE
06/05/2009	PAPER

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The time period for reply, if any, is set in the attached communication.

Interview Summary	Application No.	Applicant(s)	
	11/437,551	WILLIAMS ET AL.	
	Examiner	Art Unit	
	SHARICK NAQI	3769	

All participants (applicant, applicant's representative, PTO personnel):

(1) *SHARICK NAQI*.

(2) *RICHARD THOMAS GIRARDS, JR*.

(3)*ANGELA VERRECCHIO*.

(4)*MICHAEL ASTORINO*.

Date of Interview: *03 June 2009*.

Type: a)☐ Telephonic b)☐ Video Conference
c)☒ Personal [copy given to: 1)☐ applicant 2)☒ applicant's representative]

Exhibit shown or demonstration conducted: d)☐ Yes e)☒ No.
If Yes, brief description: _____.

Claim(s) discussed: *Independent Claims*.

Identification of prior art discussed: *N/A*.

Agreement with respect to the claims f)☐ was reached. g)☐ was not reached. h)☒ N/A.

Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: *Examiners and Applicant's Representatives discussed the pending rejections under 35 USC 112 and 101*.

(A fuller description, if necessary, and a copy of the amendments which the examiner agreed would render the claims allowable, if available, must be attached. Also, where no copy of the amendments that would render the claims allowable is available, a summary thereof must be attached.)

THE FORMAL WRITTEN REPLY TO THE LAST OFFICE ACTION MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW. (See MPEP Section 713.04). If a reply to the last Office action has already been filed, APPLICANT IS GIVEN A NON-EXTENDABLE PERIOD OF THE LONGER OF ONE MONTH OR THIRTY DAYS FROM THIS INTERVIEW DATE, OR THE MAILING DATE OF THIS INTERVIEW SUMMARY FORM, WHICHEVER IS LATER, TO FILE A STATEMENT OF THE SUBSTANCE OF THE INTERVIEW. See Summary of Record of Interview requirements on reverse side or on attached sheet.

/Michael C. Astorino/ Primary Examiner, Art Unit 3769	

PTO/SB/30EFS (06-09)
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REQUEST FOR CONTINUED EXAMINATION(RCE)TRANSMITTAL
(Submitted Only via EFS-Web)

Application Number	11/437,551	Filing Date	2006-05-19	Docket Number (if applicable)	CELG-0508	Art Unit	3769
First Named Inventor	Bruce A. Williams			Examiner Name	Sharick Naqi		

This is a Request for Continued Examination (RCE) under 37 CFR 1.114 of the above-identified application.
Request for Continued Examination (RCE) practice under 37 CFR 1.114 does not apply to any utility or plant application filed prior to June 8, 1995, or to any design application. The Instruction Sheet for this form is located at WWW.USPTO.GOV

SUBMISSION REQUIRED UNDER 37 CFR 1.114

Note: If the RCE is proper, any previously filed unentered amendments and amendments enclosed with the RCE will be entered in the order in which they were filed unless applicant instructs otherwise. If applicant does not wish to have any previously filed unentered amendment(s) entered, applicant must request non-entry of such amendment(s).

☐ Previously submitted. If a final Office action is outstanding, any amendments filed after the final Office action may be considered as a submission even if this box is not checked.

☐ Consider the arguments in the Appeal Brief or Reply Brief previously filed on _____

☐ Other _____

☒ Enclosed

☒ Amendment/Reply

☐ Information Disclosure Statement (IDS)

☐ Affidavit(s)/ Declaration(s)

☒ Other
Petition for Extension of Time Under 37 CFR 1.136(a)

MISCELLANEOUS

☐ Suspension of action on the above-identified application is requested under 37 CFR 1.103(c) for a period of months _____
(Period of suspension shall not exceed 3 months; Fee under 37 CFR 1.17(i) required)

☐ Other _____

FEES

☒ **The RCE fee under 37 CFR 1.17(e) is required by 37 CFR 1.114 when the RCE is filed.**
The Director is hereby authorized to charge any underpayment of fees, or credit any overpayments, to Deposit Account No 233050

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT REQUIRED

☒ Patent Practitioner Signature

☐ Applicant Signature

PTO/SB/30EFS (06-09)
Approved for use through 06/30/2009. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Signature of Registered U.S. Patent Practitioner			
Signature	/Stephanie A. Barbosa/	Date (YYYY-MM-DD)	2009-06-29
Name	Stephanie A. Barbosa	Registration Number	51430

This collection of information is required by 37 CFR 1.114. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these record s.

2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.